



Al Diagnostics

Transforming Global Ophthalmic Diagnostics with Artificial Intelligence



Al Diagnostics: Transforming Global Ophthalmic Diagnostics with Artificial Intelligence

1) EXECUTIVE SUMMARY

Visual impairment represents one of the greatest public health challenges of the 21st century. According to the World Health Organization (WHO), 1.1 billion people worldwide suffer from vision loss, of whom over 80% could have been prevented or treated with early and timely diagnosis. In the United Kingdom, every six minutes, a person is notified of total vision loss. This phenomenon not only impacts individual quality of life but also generates a global economic cost estimated at £320 billion annually. The situation is critical: over 600,000 patients are currently waiting for ophthalmic diagnosis or treatment in the British NHS. As the population ages and diseases such as diabetic retinopathy and glaucoma expand, early access to diagnosis becomes an urgent strategic necessity for all healthcare systems.

Facing this challenge, Championsys developed AI Diagnostics, a cutting-edge artificial intelligence platform designed to revolutionize the detection of ophthalmic diseases. By applying convolutional neural networks (CNN) to extensive databases of retinal images, AI Diagnostics enables:

- Automatically diagnosing 38 types of eye conditions with high precision.
- Facilitating rapid and accessible diagnoses in clinical or remote settings.
- Significantly reducing hospital waiting lists.
- Decreasing costs associated with late diagnoses and irreversible complications.
- Securely integrating with electronic health systems, respecting GDPR, HL7, and HIPAA standards.
- Providing a secure cloud platform where medical institutions or healthcare systems can retrain AI models, generating knowledge capital and improving diagnostic precision over time.

The technology was developed following Deloitte's Trustworthy AI framework, ensuring high ethical, security, and privacy standards. Additionally, AI Diagnostics has been officially registered as a trademark in the United Kingdom (<u>trademark</u> registration).

Al Diagnostics is not a concept: it is already a functional reality. It is currently undergoing retraining and clinical validation in the United Kingdom through strategic collaborations with:

University Hospitals Birmingham (NHS Foundation Trust)

CHAMPIONSYS

- Health Data Research UK (INSIGHT Eye Health Hub)
- NIHR Trauma MIC
- Medical Devices Testing & Evaluation Centre (MD-TEC)
- West Midlands HealthTech Innovation Accelerator (WMHTIA), supported by Innovate UK.
- Collaboration with renowned regional universities such as the University of Birmingham, Warwick Manufacturing Group, and Birmingham City University.

With its cloud-ready SaaS model, its flexibility for mobile devices, and its ability to integrate new imaging sources like OCT (Optical Coherence Tomography), Al Diagnostics is projected to become a central player in the global digital transformation of ophthalmology. In an era where early diagnosis can mean the difference between seeing and not seeing, Al Diagnostics offers a concrete tool to build a future with less blindness, less inequality in access to visual health, and greater clinical and economic efficiency.

2) INTRODUCTION: THE SILENT CRISIS OF GLOBAL VISUAL HEALTH

Human vision today faces a silent crisis: millions of people suffer from preventable vision loss, affecting their quality of life and productivity. Although medical advances have improved treatments, early detection remains a critical barrier, especially in regions with limited access to specialists or advanced equipment. Artificial intelligence (AI) offers a disruptive response, automating diagnostic processes and extending access to rural areas and congested hospitals. In this context, AI Diagnostics emerges as an innovative solution that combines deep learning, accessible SaaS platforms, and compliance with international regulations, redefining clinical diagnostics to build a more equitable and efficient visual health future.

3) GLOBAL AND REGIONAL EPIDEMIOLOGICAL CONTEXT

The problem of vision loss is massive and growing. Some current data illustrate this forcefully:

Global Overview (Source: WHO, World Report on Vision, 2019)

Vision loss represents a growing global challenge:

- More than 2.2 billion people worldwide live with visual impairment or blindness.
- Of these cases, at least 1 billion could have been prevented or have not been adequately treated.
- The main global causes include uncorrected refractive errors, cataracts, age-related macular degeneration (AMD), glaucoma, and diabetic retinopathy.



 Lack of access to early diagnostic and treatment services remains a critical obstacle, especially in low-income regions. This reinforces the need to implement technological innovation solutions that facilitate accessible and early ophthalmic diagnosis.

Official Source: World Report on Vision – OMS, 2019

The main global causes of vision loss are:

Cause	Number of people affected worldwide
Uncorrected refractive error	123.7 million
Cataracts	65.2 million
Age-related macular degeneration (AMD)	10.4 million
Glaucoma	6.9 million
Corneal opacity	4.2 million
Diabetic retinopathy	3 million
Trachoma	2 million

United Kingdom Overview (Source: NHS England, RNIB Updated 2024)

- More than 2 million people live with vision loss in the United Kingdom. Of these, more than one million have chronic and irreversible eye conditions, such as age-related macular degeneration, glaucoma, and diabetic retinopathy. Source - RNIB
- Projection to 2035: The number of people with vision loss is estimated to increase by 27%, reaching 2.8 million. This increase is mainly attributed to the aging population and the rise of chronic diseases such as diabetes. <u>Source</u> AOP (Association of Optometrists)
- Waiting lists for ophthalmic care: In November 2022, there were 628,502
 people on the waiting list for ophthalmic care in England. Of these, over 27,260
 had been waiting for more than a year. <u>Source GOV.UK Vision Profile. 2024</u>
- Annual cost of visual impairment: In 2019, the annual cost of vision loss and blindness in the United Kingdom was estimated at £36 billion. Due to the pandemic, this cost is expected to increase by £2.5 billion between 2020 and 2024. Source - RNIB Cost of Living Insight 2024.



Most Relevant Specific Diseases:

- Diabetic Retinopathy (DR): It is one of the leading causes of vision loss in people with diabetes in the United Kingdom, especially in working-age individuals. Progression without diagnosis can lead to total blindness. <u>Source:</u> <u>Diabetes UK</u>
- Glaucoma: It is one of the main causes of irreversible blindness worldwide. It is estimated that more than 500,000 people in the United Kingdom live with this condition, many without diagnosis. Source: NHS UK Glaucoma
- Macular Degeneration (AMD): Affects approximately 600,000 people in the United Kingdom and is the leading cause of legal blindness in people over 60.
 Source: Eye Surgery Guide - UK AMD Statistics

4) CURRENT CHALLENGES IN OPHTHALMIC DIAGNOSIS

Despite medical advances, traditional ophthalmic diagnosis presents structural limitations that hinder the prevention of vision loss.

- Lack of access to equipment: In Latin America, only a portion of clinics are equipped with advanced technology for ophthalmic diagnosis. This limits the early detection of chronic visual diseases and disadvantages public hospitals and rural areas. Source: Global Health Intelligence Hospirank 2022
- Shortage of specialists: Training an ophthalmologist in the United Kingdom can take between 10 and 16 years, considering university studies, general medical training, and specialized residency. This prolonged process limits the system's ability to meet growing demand, especially in the context of an aging population. Source: FacMedicine Medical training in the United Kingdom
- Late diagnoses and associated costs: Although there is no single consolidated figure for the United Kingdom, different sources estimate that late ophthalmic diagnoses can entail very high indirect costs associated with loss of productivity, social dependency, and more complex treatments. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/ Source: ABDO UK The State of Eye Health Report 2022
- Inequity of access: Inequalities in access to ophthalmic services are determined by geographical, economic, and ethnic factors. People in rural areas or with lower socioeconomic status are less likely to access preventive check-ups, leading to disparities in visual prognosis. Source: Gaceta Sanitaria-Inequality in access to medical care

The need for a disruptive solution is urgent: it is necessary to automate initial diagnosis, extend the reach of visual health, and improve technological integration in current clinical systems.



5) GENESIS AND STRATEGIC VISION OF AI DIAGNOSTICS

In 2022, **Championsys** identified a key opportunity: to democratize early ophthalmic diagnosis through artificial intelligence. Inspired by the idea of an "Instagram filter" capable of predicting eye diseases in real-time, AI Diagnostics was born.

With over 15 years of technological experience, Championsys applied its expertise to the healthcare sector, focusing on social impact, global scalability, and scientific rigor.

Our Mission

To apply artificial intelligence to transform the early detection of ophthalmic diseases, reducing preventable visual impairment and improving the quality of life for millions of people. Al Diagnostics aims not only to improve clinical processes but to generate a paradigm shift in how healthcare institutions manage visual prevention.

Our Vision

To be the global benchmark in AI-assisted ophthalmic diagnostic solutions, integrating technological innovation, clinical evidence, and ethical commitment.

Main Differentiators

- Specialization in ophthalmology: Models trained exclusively for visual pathologies.
- Accessibility: Operates on any connected device.
- Global SaaS architecture: Reaching remote areas and urban hospitals.
- Ethics and privacy: Based on Deloitte's Trustworthy AI Framework.
- Clinical self-learning: Improving accuracy based on supervised medical feedback.
- Making Artificial Intelligence available to the Teaching and Research
 Committees of healthcare systems to improve services and diagnostic quality.

Al Diagnostics is not just a platform: it is a global project to prevent avoidable blindness through collaboration between technology, medicine, and public health.

6) TECHNOLOGICAL ARCHITECTURE OF AI DIAGNOSTICS

From its inception, Al Diagnostics was designed as a robust, secure, and scalable platform, complying with the highest standards of global digital health.

1. Artificial Intelligence Engine

CHAMPIONSYS

The core of AI Diagnostics is a Convolutional Neural Network (CNN) system trained with over 35,000 retinal images. Its current capability includes the detection of 39 ophthalmic pathologies such as diabetic retinopathy, glaucoma, macular degeneration, and optic nerve abnormalities.

- Adaptive retraining: Local British datasets (INSIGHT Eye Health Hub) are being incorporated to perfect its clinical accuracy.
- Continuous self-learning: Constant improvement based on supervised medical feedback.

2. Cloud SaaS Infrastructure

Al Diagnostics operates as a SaaS platform on AWS infrastructure, offering:

- High availability and automatic scalability.
- Multi-platform accessibility: web browser, mobile, and desktop applications.
- API integrations with clinical systems (EHRs, reporting, billing).

3. International Security and Compliance

Complies with regulations:

- GDPR (Europe)
- HIPAA (USA)
- SNOMED CT and HL7 (clinical interoperability)

Implements mechanisms for:

- AES-256 and TLS 1.3 data encryption
- Automatic image anonymization
- Multi-Factor Authentication (MFA)

4. Scalability and Resilience

- Automatic scaling during traffic peaks.
- Multi-region redundancy for >99.99% availability.
- Intelligent load balancers for optimized global response.

5. Ethical Design and Al Governance

Based on Deloitte's Trustworthy AI Framework, AI Diagnostics ensures:

- Transparency and traceability in the diagnostic process.
- Active mitigation of algorithmic biases.
- Strict privacy of personal data.



• Clinical responsibility with critical human supervision.

7) VALIDATIONS AND STRATEGIC COLLABORATIONS

The Strength of Institutional Validation

To ensure that AI Diagnostics is not only a technological innovation but also a clinically viable and globally accepted solution, Championsys launched an ambitious program of validations, strategic alliances, and government support in the United Kingdom. These validations not only certify the robustness of the technological model but also open the doors to future approval as a regulated medical device (UKCA/CE) and its implementation in high-level public and private healthcare systems.

1. University Hospitals Birmingham NHS Foundation Trust

University Hospitals Birmingham (UHB) is one of the largest and most prestigious trusts in the United Kingdom, with international recognition in clinical research and medical innovation. In 2024, Championsys signed a strategic collaboration agreement with UHB to:

- Retrain the AI Diagnostics model using local ophthalmological datasets provided by the Health Data Research UK INSIGHT Eye Health Hub.
- Validate the clinical efficacy of the software in simulated and real environments.
- Develop usability studies in collaboration with the NIHR Trauma Management MedTech Cooperative and the Medical Devices Testing & Evaluation Centre (MD-TEC).

Official Source: <u>University Hospitals Birmingham</u>

2. WMHTIA - West Midlands Health Tech Innovation Accelerator

Al Diagnostics was selected by the WMHTIA program as one of the Health Tech projects with the highest potential impact for the West Midlands region. Thanks to the support of WMHTIA, Championsys achieved:

- Access to specialized mentorship in medical innovation and commercialization of healthcare technologies.
- Partial financial support through regional innovation funds.
- Visibility at strategic events such as Birmingham Tech Week.



See publication: WMHTIA LinkedIn

3. Trademark Registration in the United Kingdom

In 2023, AI Diagnostics was officially registered as a trademark in the United Kingdom, and in Europe in 2024, protecting its intellectual property and ensuring exclusive commercial exploitation in British and European territory.

Official registration: <u>Trademark Elite - UK00003977200</u>. <u>Official EU registration</u> 019023775

This step reinforces Championsys' position as an emerging leader in Al-based digital health innovation. Additionally, Al Diagnostics has a pending innovation patent. Application number: GB2415137.5.

4. Strategic Participations in High-Level Events

To position AI Diagnostics in the global Health Tech ecosystem, Championsys actively participated in:

- Birmingham Tech Week 2024 Official presentation of AI Diagnostics. (see publication)
- Medtech Innovation Expo 2024 Exhibition of the solution to European hospitals, clinics, and governments.
- London Tech Week 2024 Strategic meetings with investors, accelerators, and healthcare organizations.

These events have enabled the consolidation of alliances, opened market opportunities, and validated the relevance of Al Diagnostics in international forums.

5. Evolutionary Development of an Image Acquisition Device

With the aim of facilitating access to ophthalmic diagnoses in remote environments, Championsys, in collaboration with the Warwick Manufacturing Group (WMG) at the University of Warwick, is promoting the evolutionary development of a portable device for capturing fundus images. This device seeks to:

- Enable the acquisition of clinical quality images in rural areas, low-complexity hospitals, and mobile visual prevention campaigns.
- Reduce dependence on expensive ophthalmic equipment.
- Facilitate direct integration with the AI Diagnostics platform for a continuous flow of data and automatic interpretation.



The alliance with WMG ensures advanced engineering standards, clinical ergonomics, and optimization for scaled production in future phases of the project.

6. Eye Tracking Tool

In collaboration with Birmingham City University, Championsys has developed an eye tracking tool that evaluates the technical quality of ophthalmic images before they are processed by the Al Diagnostics Al. This solution analyzes parameters in real-time such as:

- Eye centering
- Stability during capture
- Illumination level
- Focus

Based on these criteria, the tool determines whether the image meets the minimum standards to be interpreted by the system. This reduces the margin of error, prevents false diagnoses, and optimizes the use of the AI engine, ensuring that only clinically valid images are processed. This functionality is key to ensuring diagnostic consistency, especially in decentralized capture environments or with non-specialized personnel.

8) PRELIMINARY RESULTS AND MEASURED KPIS

Al Diagnostics has shown outstanding results in its initial validation in Latin America and the United Kingdom, confirming its ability to transform the detection of ophthalmic diseases and reduce preventable visual impairment.

1. Diagnostic Accuracy

Pathology	Accuracy / Sensitivity
General Diagnosis	91.4%
Diabetic Retinopathy (severe)	97%
Diabetic Retinopathy (mild)	60%
Glaucoma (optic alterations)	93%
Macular Degeneration (AMD)	89%

CHAMPIONSYS

Al Diagnostics included numerous vitreoretinal pathologies with higher current prevalence, among them vascular obstructions (arterial and venous), optic nerve alterations, macular structure alterations, fundus neoplasms, hypertensive and diabetic retinopathy (with their respective stages), alterations due to high myopia, and other less frequent but clinically important pathologies in a typical ophthalmological consultation.

Regarding vascular obstructions, their success rate was high for both venous and arterial (80.3% and 60% respectively).

With respect to Diabetic Retinopathy, the algorithm presents a correct classification according to its clinical stage, and although all stages were diagnosed with a high percentage of success, the more advanced stages had greater diagnostic precision (83.3% accuracy for the blurry fundus with suspected PDR category and 97% for the no suspected PDR category).

All macular alterations had good discrimination between pathological/normal (average error percentage of 1.8%); something to highlight considering that this type of pathology can be easily overlooked, especially in its initial stages or in untrained eyes.

Of the metrics we consider most valuable is the ability to detect Diabetic Retinopathy in its earliest stage in 60% of cases, taking into account that these are subclinical cases and that their early detection (at this stage) can help prevent irreversible damage to the optic nerve.

2. Clinical Impact on Workflows

Indicator	Result
Average diagnosis time	< 60 seconds
Time reduction compared to manual consultation	Up to 85%
Physician adoption in clinical tests	83%
Medical user satisfaction	90% rated as "very intuitive"



3. Estimated Economic Impact

Concept	Estimate
Cost reduction for preventable blindness	Up to 60%
Potential savings for healthcare systems	£115 million/year in UK

Implications of these Results

- Potential to drastically reduce waiting lists in ophthalmic consultations.
- Significant savings in clinical and social costs.
- ightharpoonupReal prevention of chronic blindness as a consequence of diabetes.
- Greater equity in access to early visual diagnosis, especially in vulnerable areas.

9) PROJECTED IMPACT ON PUBLIC HEALTH AND COSTS

Based on clinical and economic modeling, AI Diagnostics has the potential to structurally transform public and private visual health.

1. Reduction of Ophthalmic Waiting Lists

Indicator	Current Situation	Al Diagnostics Impact
Patients on waiting list (NHS UK)	600,000+	Projected reduction: -25% in 3 years
Average waiting time	42 weeks (target 18 weeks)	Acceleration of triage and critical referrals

Source: NHS England Performance Reports

2. Prevention of Avoidable Blindness Cases



Concept	Projection
New cases of preventable blindness without intervention	39,000/year
Projected reduction with AI Diagnostics	-27% in 5 years

Improvement in quality of life and savings in rehabilitation, visual aids, and pensions.

3. Economic Impact: Potential Savings for the NHS

Concept	Projected Savings
Reduction of clinical and social costs	£115 million/year

These funds could be reinvested in new prevention campaigns, acquisition of portable devices, and medical training.

4. Impact on Equity of Access to Visual Health

- \boxed{V} Implementation in rural areas without specialized ophthalmologists.
- ✓ Mobile screening with accessible devices.
- Reduction of ethnic and socioeconomic inequalities in access to visual diagnosis.

5. Environmental Impact (Indirect)

- ✓ Reduction of unnecessary patient travel.
- ☑ Digitization of processes and reduction of paper use.
- ☑Optimization of imaging equipment use.

In summary:

Al Diagnostics is not just a clinical solution, but a comprehensive platform that:

- Improves clinical outcomes.
- Reduces systemic costs.
- Expands equitable access to care.
- Optimizes existing healthcare resources.



• Prepares healthcare systems for future demographic challenges.

10) STRATEGIC ROADMAP 2025-2028

Championsys has designed a 2025-2028 Roadmap to consolidate AI Diagnostics as a global leader in AI-based visual health, focusing on regulatory certifications, geographical expansion, technological innovation, and strategic alliances.

Main Phases:

Year	Key Objectives	Main Goal	
2025	- Clinical retraining with UK data (UHB) Application for UKCA and CE certification Hospital implementation for clinical validation No SaaS commercialization until medical device approval.	Technical and clinical validation + regulatory certification application	
2026	- Implementation in hospitals in Spain and LATAM (Argentina, Uruguay, Chile, Mexico) Legal and technical adaptation to each market Institutional alliances with regional stakeholders.	International use cases + validation expansion	
2027	- Inclusion of new diagnoses (OCT, keratoconus, etc.) Integration with low-cost mobile devices Development of multimodal AI for retina and brain Obtaining medical device approval.	Complete certifications + commercial enablement of the SaaS model	
2028	- Deployment in LATAM, Africa, and Asia Alliances with NGOs and public healthcare systems Scaling of the SaaS model and global infrastructure.	Al Diagnostics operational in 15+ countries and global consolidation	

Investment in Continuous Innovation

- Annual updates of AI models based on new clinical evidence.
- Ethical audits to reinforce trust in Al.
- Evolution of cloud infrastructure to guarantee global security, scalability, and performance.



In summary:

The 2025-2028 Roadmap aims to scale the impact of AI Diagnostics, building a living, evolving platform and a global benchmark in AI-assisted visual prevention.

11) CONCLUSION AND CALL TO ACTION

Every six minutes, a person loses their sight in the United Kingdom. Globally, over 2.2 million people live with visual impairment. The vision crisis is not just clinical: it is social, economic, and ethical. Al Diagnostics emerges as a concrete response, using specialized Al in ophthalmology to:

- ✓ Facilitate early diagnosis, without geographical or economic barriers.
- ✓Improve the efficiency of healthcare systems.
- ✓ Reduce clinical costs and expand equity in access.

What have we achieved?

- A secure, scalable, and clinically validated platform.
- Alliances with University Hospitals Birmingham, INSIGHT Hub, and support from Innovate UK and WMHTIA.
- Preliminary results showing reduction in waiting lists, diagnostic improvement, and economic savings.

What's next?

- UKCA/CE certification as a medical device.
- Expansion to new global markets.
- Incorporation of OCT and new clinical modalities.
- Consolidation as a global benchmark in Al-assisted visual health.

A call to action

Now, more than ever, is the time to act.

- Hospitals and clinics: Integrate AI solutions for early diagnosis.
- Governments: Incorporate ethical AI into visual prevention strategies.
- Foundations and NGOs: Promote accessible screening campaigns.
- Researchers: Strengthen the scientific evidence of new AI applications.

Because preventing blindness is possible. Because democratizing visual access is a right. Because technology, when applied with ethics and passion, changes lives.



Al Diagnostics:

Seeing today, to see better tomorrow.

References and Sources

Table of official sources used in the development of the AI Diagnostics document.

N°	Topic / Description	Source	Link
1	Al Diagnostics Presentation at Birmingham Tech Week	Championsys UK LinkedIn Post	https://www.linkedin.com/feed/update/urn:li:activity:7254524133605040129
2	Global Visual Impairment Statistics	World Health Organization	https://www.who.int/publications/i/item/world-report-on-vision
3	Clinical Validation with University Hospitals Birmingham	University Hospitals Birmingham NHS Trust	https://www.uhb.nhs.uk/
4	INSIGHT Eye Health Hub Collaboration	Health Data Research UK - INSIGHT Hub	https://www.insight.hdrhub.org/
5	Publication on West Midlands Health Tech Innovation Accelerator	Championsys UK LinkedIn Post	https://www.linkedin.com/feed/update/urn:li:activity:7270127483578982401
6	Costs of Visual Impairment in the United Kingdom	RNIB Report 2024	https://www.rnib.org.uk/
7	WMHTIA Selection and Support	WMHTIA Official	https://wmhtia.org.uk/
8	Note on Argentine Startups in the United Kingdom (Al Diagnostics mentioned)	Diario La Nación	https://www.lanacion.com.ar/economia/negocios/destino-tech-reino-unido-busca-seducir-a-las-startups-argentinas-nid06072024/



9	Innovate UK Co-financing	Innovate UK - Biomedical Catalyst	https://www.ukri.org/councils/innovate-uk
10	Publication on collaboration with NIHR and Health Data Research UK	Championsys UK LinkedIn Post	https://www.linkedin.com/posts/championsys-uk-eu_nihr-birmingham-universityofbirmingham-activity-7187165557815730177-yK7
11	Impact of Health Tech Innovation Accelerator	WMHTIA LinkedIn Post	https://www.linkedin.com/posts/wmhtia_wmhtia-grant-funding-to-empower-innovators-activity-7231969692574269441-Bjsl
12	AI Diagnostics Trademark Registration in the UK	UK IPO (Trademark Elite)	https://www.trademarkelite.com/uk/trademark/trademark-detail/UK00003977200/AI-DIAGNOSTICS
13	Championsys Participation in London Tech Week	Championsys UK LinkedIn Post	https://www.linkedin.com/posts/championsys-uk-eu_londontechweek2024-latac-techinnovation-activity-7206354518454767617-zjzN
14	Participation in Medtech Innovation Expo 2024	Championsys LinkedIn	https://www.linkedin.com/posts/championsys_medtechexpo-medtech-medtechinnovation-activity-7204154895376015361-up5G
15	Impact on NHS Waiting Lists and Visual Prevention	NHS England Performance Reports	https://www.england.nhs.uk/statistics/stat istical-work-areas/rtt-waiting-times/
16	Economic Impact of Visual Impairment	RNIB Economic Impact Report	https://www.rnib.org.uk/professionals/heal th-social-care-education-professionals/re search-and-statistics/
17	Global Diabetic Retinopathy Data	International Diabetes Federation	https://idf.org/

