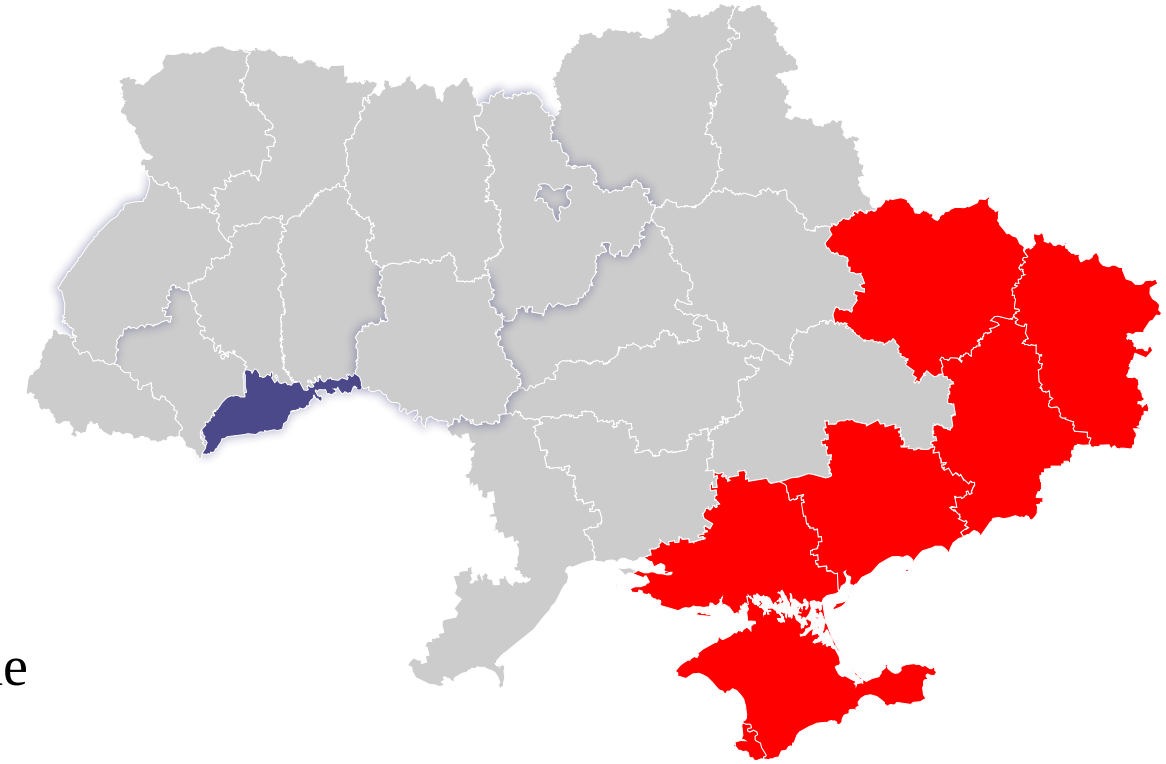
Artificial intelligence for mass screening of diabetic retinopathy: proceeding to national level in Ukraine during 2022-2023

O. Chernenko, K. Goncharuk, A. Korol

BACKGROUND. ONE YEAR AGO

- The first pilot screening project in Chernivtsi region
- The B2C format was used in collaboration with the most active diabetes patient organization – the Ukrainian Diabetes Federation
- Result: signs of diabetic retinopathy were detected in 30% of individuals with a previously diagnosed case of diabetes



93% sensitivity

86% specificity

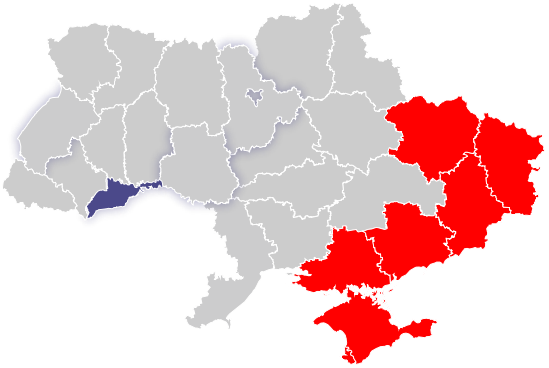
Screening model accuracy

– *War affected regions*

– *CheckEye screening is implemented*

CHECKEYE

Background. One year ago



The first article has been prepared for the peer-reviewed "Journal of Ophthalmology."

Presentations:

- IDF 2022,
- EURO RETINA,
- Filatov Memorial Lectures,
- EHMA 2023

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Detecting diabetic retinopathy using an artificial intelligence-based software platform: a pilot study

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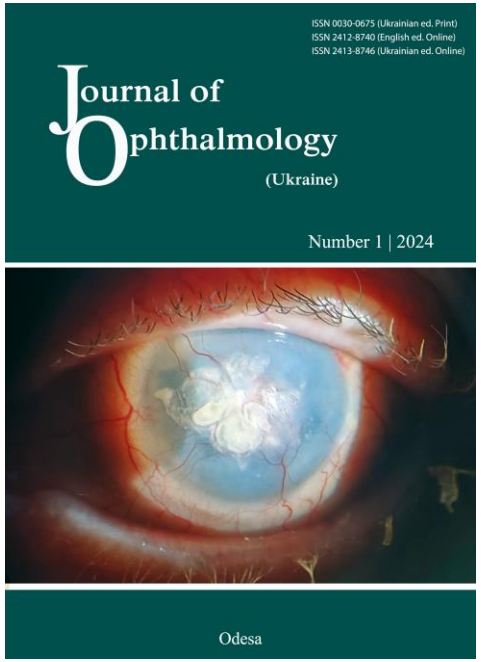
Purpose: *To examine the potential for the detection of diabetic retinopathy (DR) using the artificial intelligence (AI)-based software platform Retina-AI CheckEye©.*
Material and Methods: *This was an open-label, prospective, pilot observational case-control study for the detection of DR using an AI-based software platform. The study was conducted at the sites of healthcare facilities in Chernivtsi oblast. Four hundred and eight diabetics and 256 non-diabetic controls were involved in the study. All fundus images were analyzed using the artificial intelligence (AI)-based software platform Retina-AI CheckEye©. Receiver operating characteristic (ROC) curve analysis was performed to determine the sensitivity and specificity of the DR diagnosis method.*
Results: Using the AI-based software platform, signs of DR in at least one eye were detected in 143 diabetics (22% of total study subjects (664 individuals; 1328 eyes) or 35% of the diabetics (408 patients)). No DR signs were detected in 322 individuals (48% of total study subjects). In 199 individuals (30% of total study subjects), the results were not obtained due to the features of the optical media and presence of certain eye diseases (in most cases, unilateral cataract or corneal opacity). This trial found 93% sensitivity and 86% specificity for the Retina-AI CheckEye-assisted detection of DR.
Conclusion: *An AI-based software platform, Retina-AI CheckEye©, has been for the first time developed in Ukraine. The platform was demonstrated to have a high accuracy (93% sensitivity and 86% specificity) in diagnosing DR in diabetic patients and can be used for large-scale DR screening.*

Keywords:
diabetes mellitus, diabetic retinopathy, artificial intelligence, disgnostics



■ – *War affected regions*
■ – *CheckEye screening is implemented*

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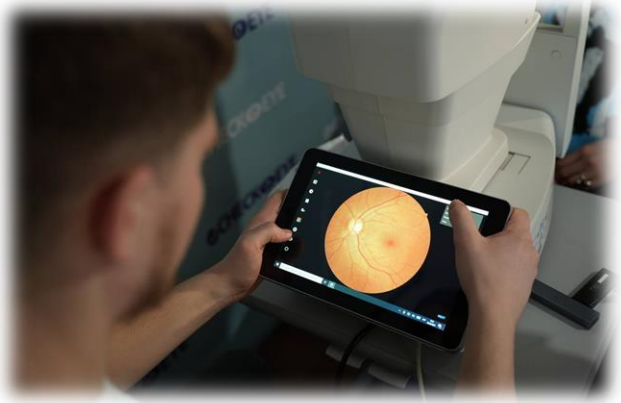
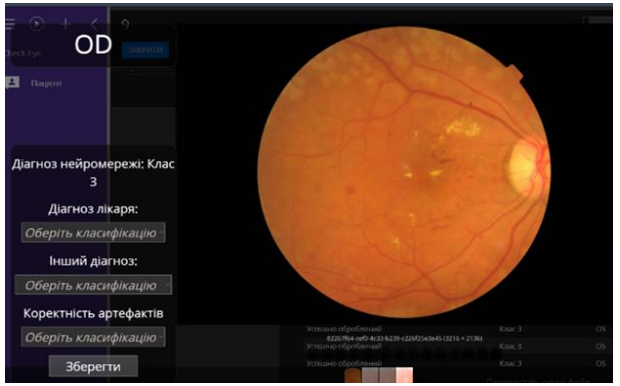
Our purpose, established for 2023-2024

- **To expand AI-driven mass screening of diabetic retinopathy in Ukraine in wartime, to evaluate its accuracy**





Methods:

STUDY DESIGN

multicentral, prospective, open-label, observational

TIME FRAME

July 2023 till March 2024

REGIONS

Central, Western and South parts of Ukraine

INCLUSION CRITERIA

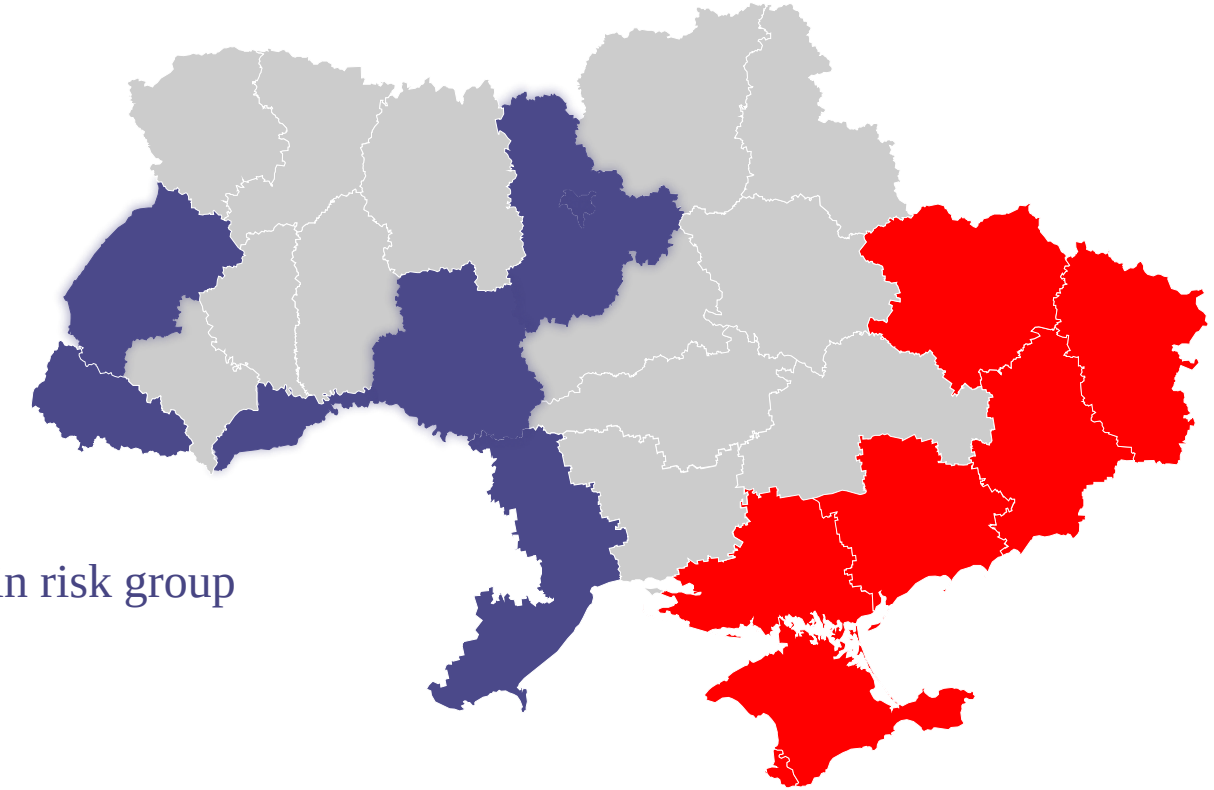
Patients with documented DM type 1 and 2, and those in risk group

EXCLUSION CRITERIA

Patients under 18 y.o.

IMPLEMENTING MODEL

B2B2C, collaborating with public & private healthcare institutions



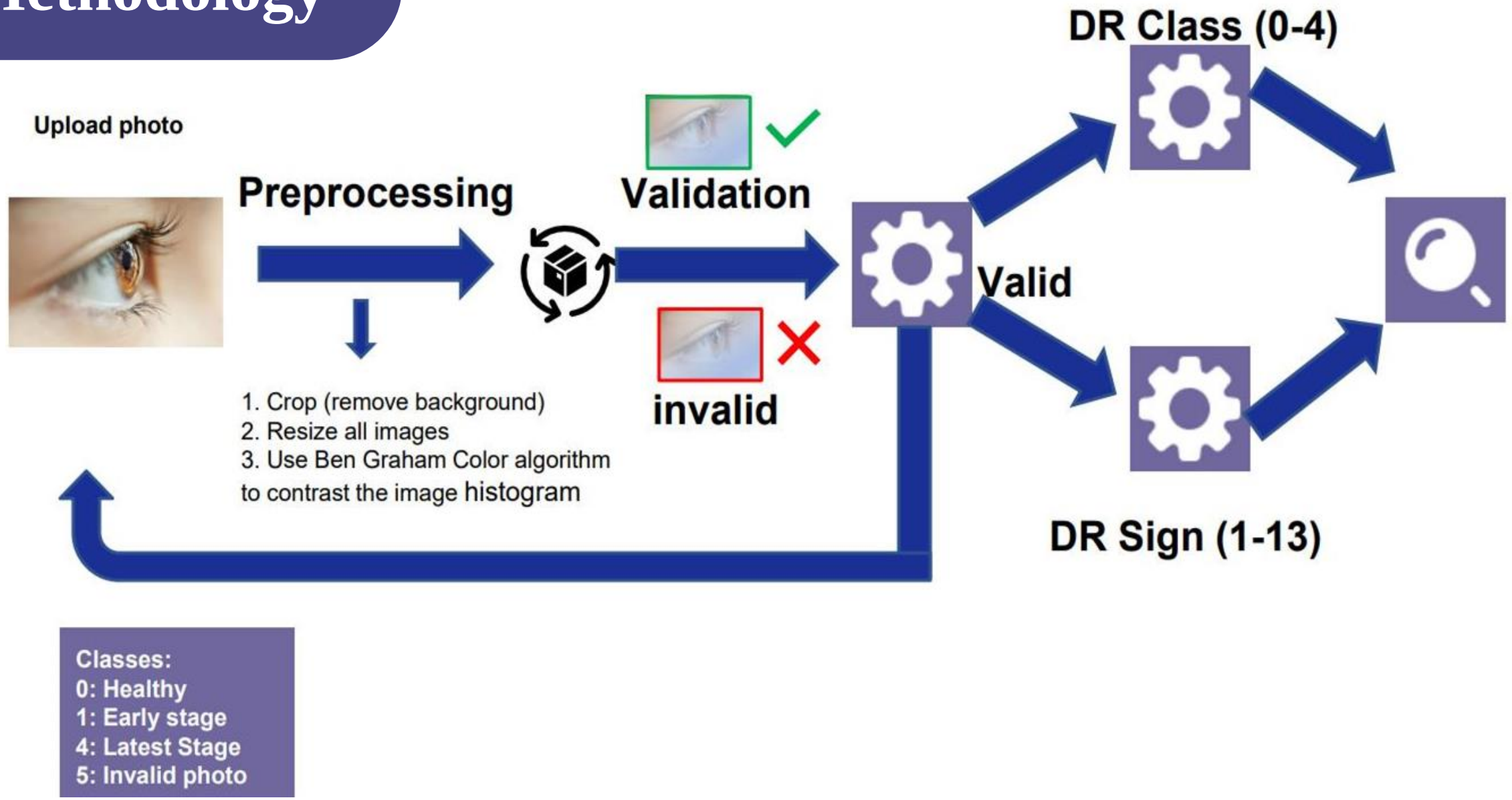
– *War affected regions*

– *CheckEye screening is implemented*

Methods:

- Non-mydriatic fundus camera - the field of view of 45°
- One field color photo with center in fovea for each eye
- Cloud-based Retinal-AI CheckEye©
- ROC curve analysis was performed to determine the sensitivity and specificity of the DR diagnosis method.

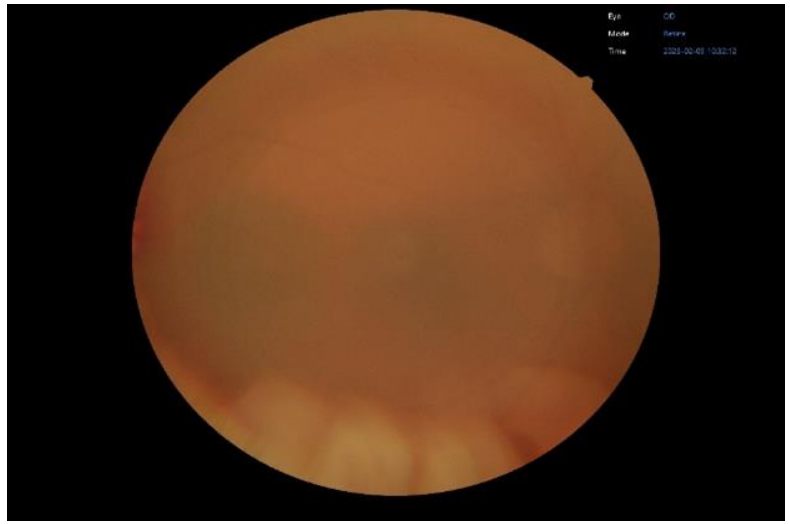
Methodology

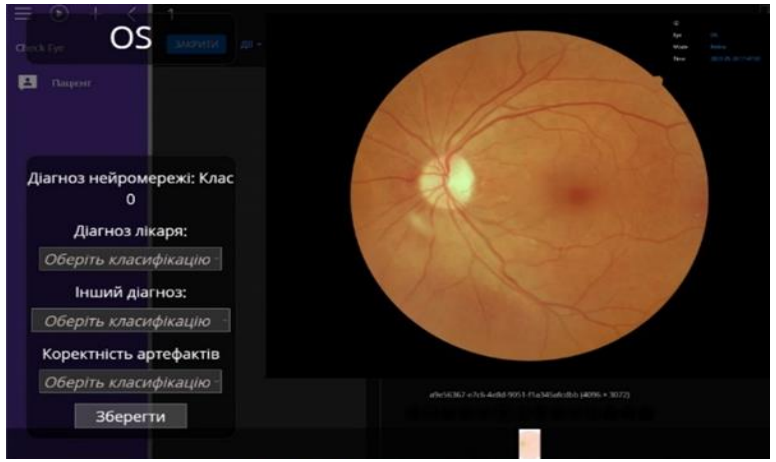


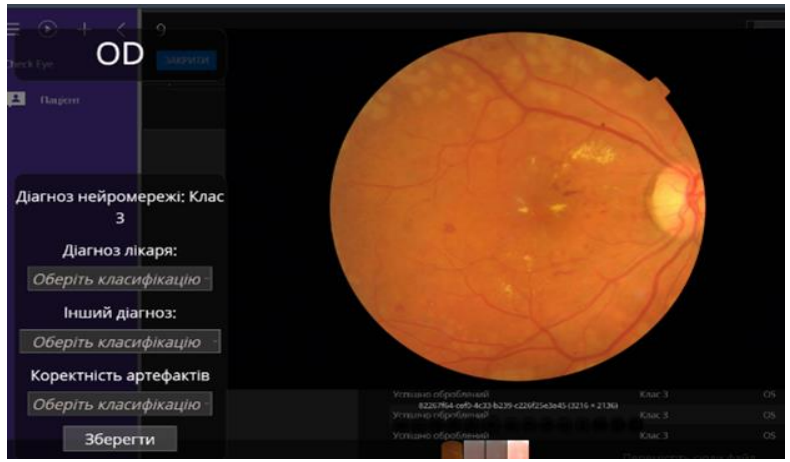
Methodology

The first stage
validation

The second stage
verification







Results

Health care institutions\patients

	Number of units	Screened without DM	Screened with DM
Privat health care	1	109	203
Privat mobile sites	3	309	17
Government first line	2	747	428
Government second-third line	4	555	946
NGO	1 - Red Cross	14	18
Total	11	1734	1612

58 y.o.

Mean age of patients

59 y.o.

Mean age of patients with DM

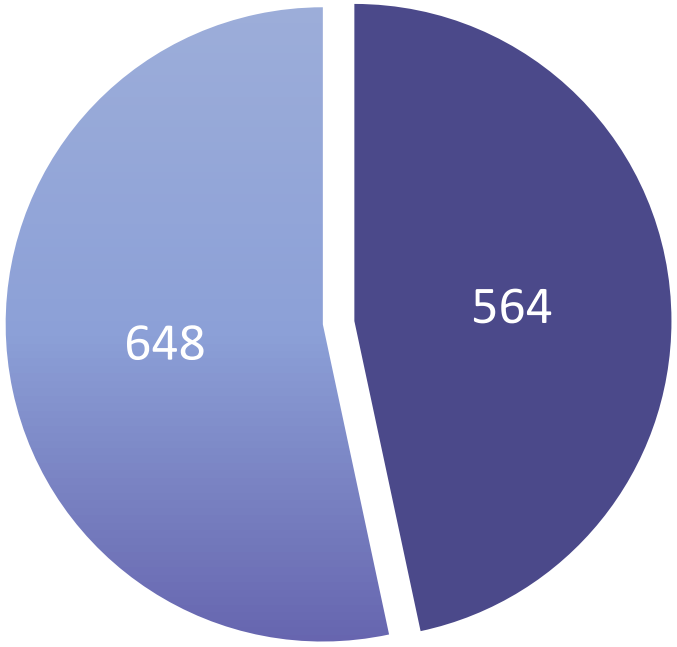
11 y. 6 m.

Mean history of DM

Results

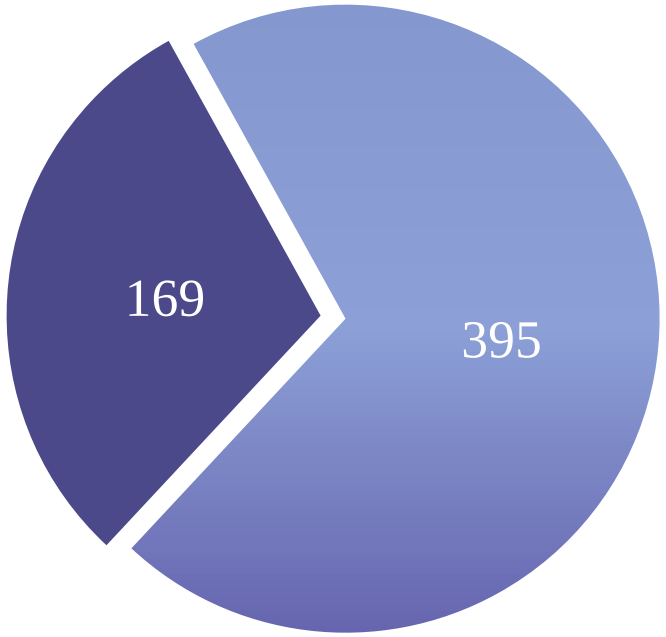
Diabetic patients and DR

Detecting of DR



- **1 612** diabetic patients
- **3 224** eyes

First manifestation of DR

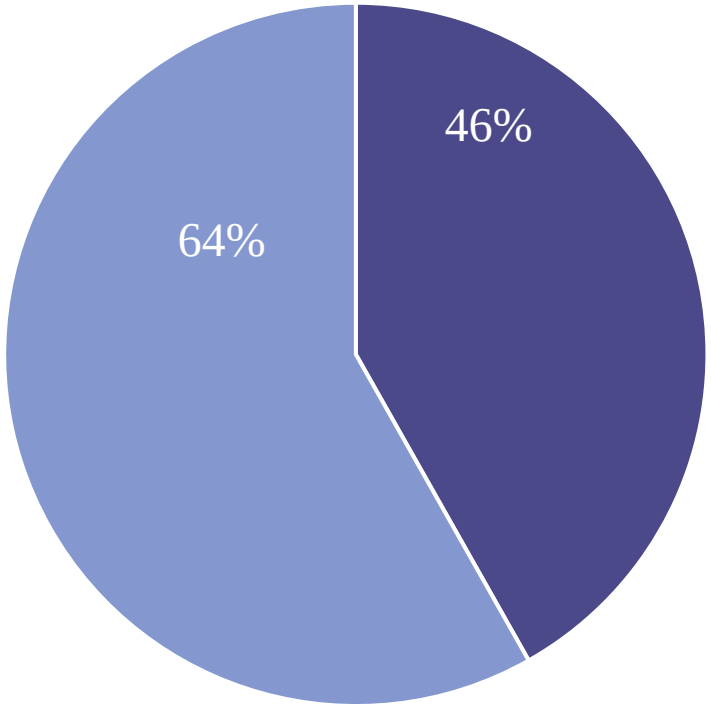


- **35% of the diabetic patients were detected DR in at least one eye**
- **30% of persons with detected DR learned for the first time that they had diabetic retinopathy**

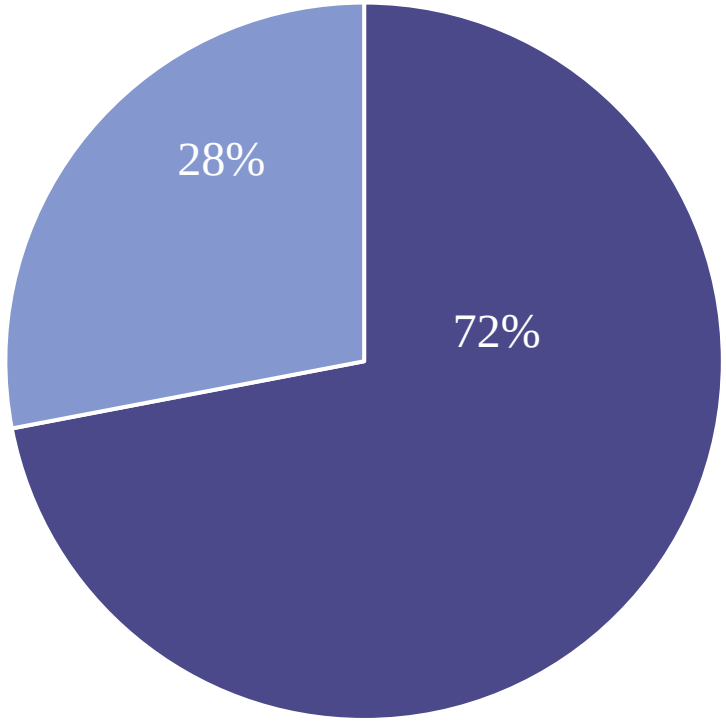
Results

Proportion under/over 64 y.o.

General proportion with DM

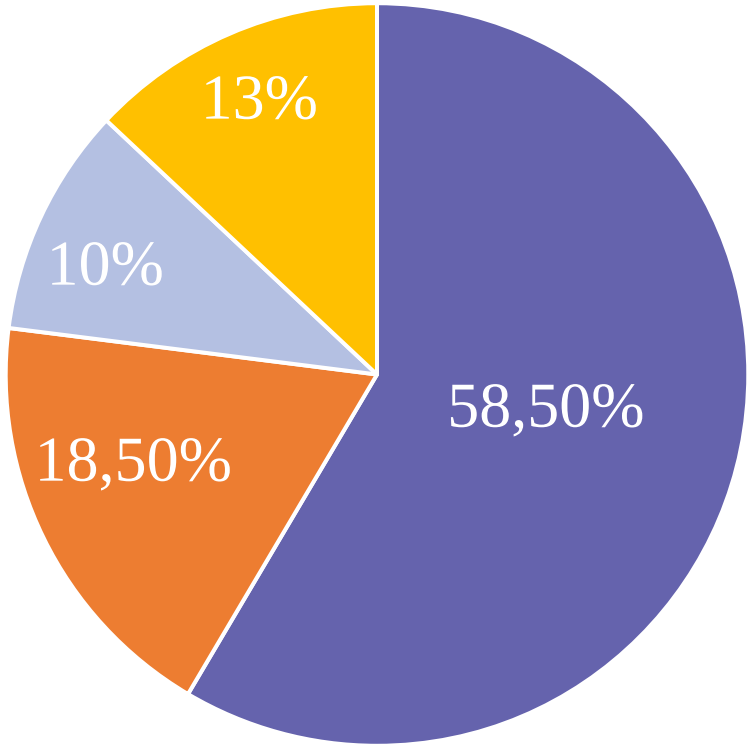


Presence of DR in patients with DM under 64 y.o.

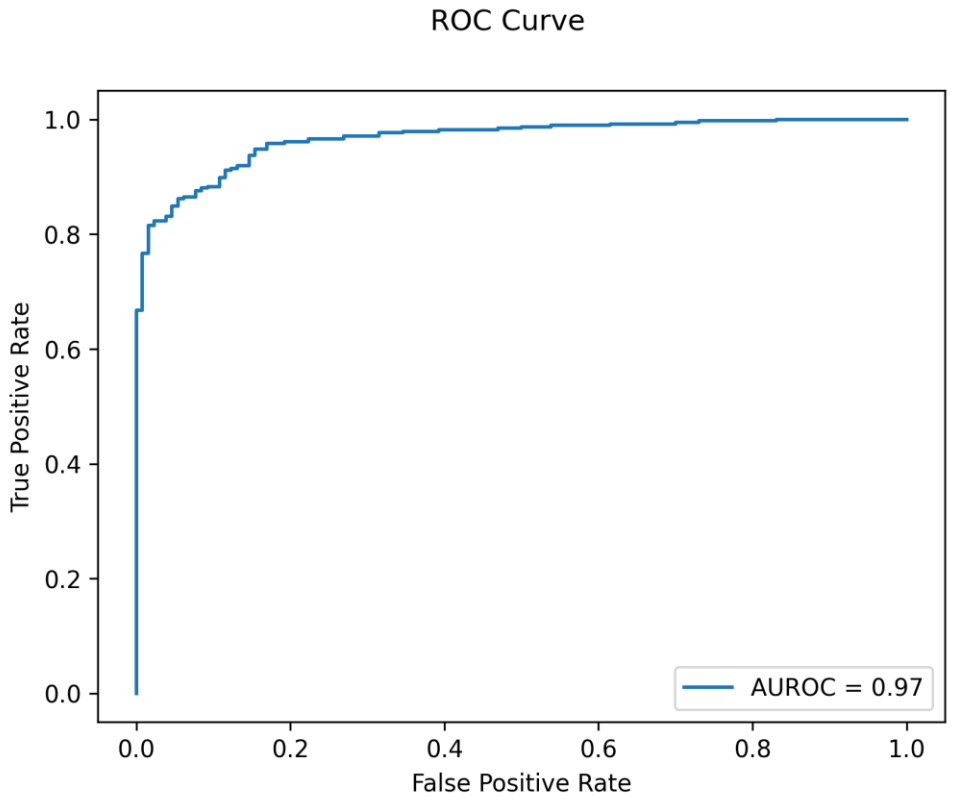


Results

DR in patients under 64 y.o.



Results



- 95% sensitivity (↑), 84% specificity (↓)
- AUC 0.97
- Adding a second neural network allowed us to achieve a **combined specificity of up to 90%**

Calculation Model of probable number of patients to be treated

Official data on DM in Ukraine	Non-official DM in Ukraine by UDF
People with Diabetes	
1.3 million	**2.3 million**
Calculated number of people with Diabetic Retinopathy (28%)	
364 000	**644 000**
23% need to be treated *(severe non proliferative + proliferative stages)*	
83 720	**148 120**

Discussion

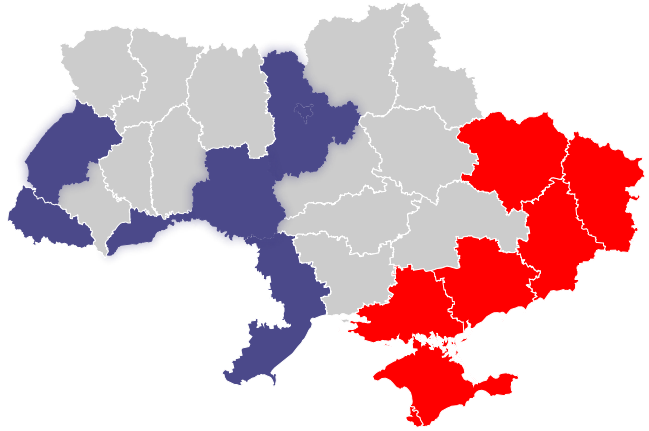
Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices. Abramoff MD, Lavin PT, Birch M, Shah N, Folk JC. *NPJ Digit Med*. 2018
In a prospective study, Abràmoff *et al*.achieved 87.2% sensitivity and 90.7% specificity. Their IDx-DR (Digital Diagnostics, Corville, IA, USA) was the first US Food and Drug Administration (FDA)-approved autonomous AI device in medicine, designed to detect diabetic retinopathy and diabetic macular edema

Improved Automated Detection of Diabetic Retinopathy on a Publicly Available Dataset Through Integration of Deep Learning, Abràmoff MD, Lou Y, Erginay A, Clarida W, Amelon R, Folk JC, et al, *Invest Ophthalmol Vis Sci*. 2016
Abràmoff *et al*. reported a sensitivity of 96.8% and specificity of 87.0% with an area under the receiver operating characteristic curve (AUC) of 0.980 in the detection of referable DR.

Automated identification of diabetic retinopathy using deep learning. Gargeya R, Leng T. *Ophthalmology.* 2017
A total of 75 137 publicly available fundus images from diabetic patients were used to train and test an artificial intelligence model to differentiate healthy fundi from those with DR. Model achieved a 0.97 AUC with a 94% and 98% sensitivity and specificity, respectively, on 5-fold cross-validation using our local data set. Testing against the independent MESSIDOR 2 and E-Ophtha databases achieved a 0.94 and 0.95 AUC score, respectively.

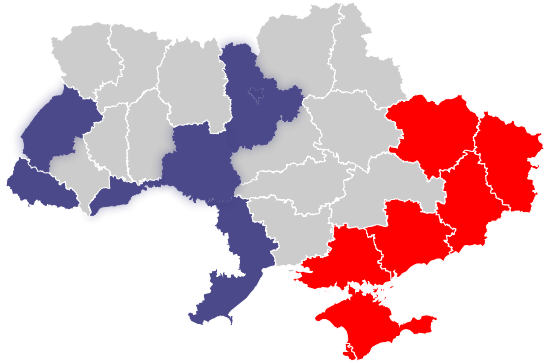
Development and validation of a deep learning system for diabetic retinopathy and related eye diseases using retinal images from multiethnic populations with diabetes. Ting DSW, Cheung CY, Lim G, Tan GSW, Quang ND, Gan A, et al. *JAMA*. 2017
Ting *et al*. validated the application of AI in DR screening using real-world data from 10 datasets in 6 countries with an AUC of 0.936, sensitivity of 90.5% and specificity of 91.6% in detecting referable DR and an AUC of 0.958, sensitivity of 100%, and specificity of 91.1% in detecting vision-threatening DR.

Key findings



- Screening has been implemented in **30% of regions free from battlefield.**
- Alongside the B2C format in collaboration with the most active diabetic patient organization – the Ukrainian Diabetes Federation, we are actively working in the **B2B2C format**, **mobile format**, and also initiating cooperation in the **B2G format** (goal for the current calendar year).
- As the system processes large volumes of data, the detection results for DR remain consistent: **signs of diabetic retinopathy were detected in 35% of individuals with a previously diagnosed case of diabetes.**
- Signs of diabetic retinopathy are detected in **28% of individuals under the age of 64 (working age)** with a previously diagnosed diabetes – in contrast to the commonly accepted statistic of 10%.

Key findings



- **The accuracy of the screening model has been improved:** currently, it has 95% sensitivity and 90% specificity, with an AUC of 0.97. Our system demonstrates high accuracy, comparable to or exceeding that of humans, especially in large-scale applications and over extended periods, as AI does not tire, experience emotions, or get distracted.
- During wartime, our system showed **high accessibility and affordability for mass screening** of DR, including due to technological accessibility and flexibility in choosing screening organization formats.
- The subsequent implementation of diabetic retinopathy screening “CheckEye” will help preserve the vision of up to 150,000 residents of Ukraine, which is of immense importance for the country's survival and post-war recovery.
- Further expansion of the diabetic retinopathy screening method “CheckEye” will help preserve the vision of up to **100 million people worldwide by 2050**, which is of immense importance for global healthcare and wellbeing.

LET'S SCREEN TOGETHER

- Ask any questions
- Book an introductory meeting with CheckEye founder and team
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  ochernenko@check-eye.com