DIGI4Care Final Fact Sheet - Pilot 1

Digital prevention and screening for diabetic retinopathy and cardiovascular risk and diseases

1. Title and overview

Title of the Clinical Pilot

Piloting the introduction of digital solutions in prevention and screening in the field of diabetes and cardiovascular diseases.

Brief summary of objectives and scope

Pilot 1 tested digital screening models for diabetic retinopathy (DR) and cardiovascular diseases (CVD) and CVD risk in real-world outpatient settings across Bulgaria, Hungary, Romania and Slovakia. The common DR pre-screening or screening component used digital, tabletop, automated non-mydriatic fundus cameras and CE-certified AI software in general practice (GP) offices and diabetes clinics to detect sings of DR and support structured referral to ophthalmology. The Bulgarian site also implemented a CVD screening pathway into GP practice with cardiologist referral option using the Hubis telemedicine screening station, SCORE2 risk assessment and CheckPoint Cardio (CPC) monitoring for high-risk patients.

The pilot aimed to bring screening closer to routine care locations, improve screening uptake, generate results on usability and workflow fit, and identify the operational conditions needed for scale-up.

Pilot timeline and current phase

January 2025 - March 2026, with site-specific extensions where required.

2. Key milestones achieved

- Site-level protocols and project-level methodology were developed and adapted to national and local environments.
- Fundus cameras, AI software and supporting digital tools were procured and deployed; Bulgaria also deployed Hubis and CPC technologies for CVD screening.
- Ethical approvals, HCP training, patient information and consent procedures were completed.
- Pre-screening or screening was performed in GP and diabetes clinics and mobile screening settings.
- Ophthalmology referral arrangements were established differently by country; Slovakia developed a dedicated digital scheduling application to support appointments with ophthalmologists.

3. Participant and site update

Number of participants enrolled vs. target and geographical coverage

Site	Participants / coverage	Target status
Hungary	98 DR screening participants by March 2026; GP practice and mobile screening settings; 95 patient experience questionnaires. One GP office and mobile screening programme.	Target patient number reached after extension;
Slovakia	170 analysable DR screening participants; one GP location, multiple diabetology locations after camera relocation.	Below original target; approximately below 50% of initial target due to administrative burden and HCP withdrawal. However, the initial patient number recorded at project start was exceeded
Romania	49 patients enrolled in a diabetology clinic setting;, 49 patient experience questionnaires.	Target range was reached.
Bulgaria - DR	153 patients included in final DR analysis; outpatient healthcare centre with GP and ophthalmology collaboration, 153 patient experience questionnaires.	Near target / meaningful volume achieved.

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Bulgaria - CVD	217 CVD screening participants via Hubis; 112 high-risk referrals; 50 patients underwent 48-hour CPC monitoring.	CVD target exceeded; new cardiovascular disease diagnosed in 24 patients.

4. Technology deployment and usage

Status of digital technologies implemented

Technology	Deployment and usage
DR screening	Digital, tabletop, automated non-mydriatic fundus cameras connected to AI supported DR detection software (MDR Class IIb medical device) at all sites. tablet/app support for consent and ophthalmology scheduling application (Slovakia)
Bulgaria CVD screening	Hubis telemedicine station for multi-parameter screening and SCORE2 risk assessment; CPC for 24-48-hour ambulatory cardiac monitoring of high-risk patients.
Data and workflow tools	Site-specific on-site data collection and cloud-based solutions digital patient experience questionnaires, digital referral/scheduling process.

5. Data and findings

Data collection and assessment

The evaluation combined site-specific activity data, technology logs or platform outputs where available, patient and HCP feedback.

Site-specific results

Site	Screening results and acceptance
Hungary	Pre-screening result: 68.4% negative, 14.3% positive, 17.4% undetermined. No false negative DR patients were identified by the end of pilot related ophthalmology follow-up; false positives occurred. Patients welcomed the initiative, although travel to Budapest was not feasible for all.
Slovakia	Among 170 analysable patients: 86% negative and 14% positive. Undetermined patient number was not evaluated due to data management compliance restrictions. Patients welcomed screening at the diabetologist/GP and 88% would repeat the examination. Average image acquisition/evaluation process took 11 minutes; scheduling an ophthalmology appointment via tablet took 15 minutes.
Romania	Among patients with at least one analysable eye: 10.2% positive, 73.5% negative, 16.3% undetermined. Point-of-care access addressed a major barrier, as distance was frequently cited as a reason for not attending ophthalmology screening.
Bulgaria - DR	14.4% positive, 80.3% negative, 5.3% undetermined. Collaboration with ophthalmology enabled feedback and identification of false-positive cases.
Bulgaria - CVD	High patient satisfaction: 87.6% very satisfied with time, 88.5% very satisfied with comfort, 91.2% would definitely repeat the examination. CPC monitoring detected abnormalities such as first-degree AV block and premature atrial/ventricular depolarisation.

6. Challenges and risk management

Identified issues

- Administrative burden for consent, questionnaires, documentation and referral was a major barrier, especially in Slovakia and GP settings.
- Image capture could require repeated attempts in certain groups of patients or in the presence of unknown cataract, media opacity, ptosis or miosis.
- Connectivity and upload speed affected workflow, especially in Hungarian mobile screening events.

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- Follow-up attendance at ophthalmology remained difficult for some patients due to distance, or limited appointment availability.
- HCP technology acceptance was generally positive, but the number of enrolled HCPs was low to evaluate Technology Acceptance Model questionnaire results.

Actions taken or proposed to mitigate risks

Pilot teams used local workflow adaptation, additional training, technical support, equipment replacement or relocation, improved scheduling/referral arrangements, and supplier engagement to maintain implementation feasibility.

7. Next steps and adjustments

Planned activities / scale-up adjustments necessary

- Simplify administrative steps and digital forms; consider screening-assistant roles where possible.
- Strengthen local referral options and telemedical ophthalmology review to reduce travel barriers.
- Standardize guidance for undetermined images, repeated captures and patient exclusions.
- Define reimbursement, staffing and workflow models for routine implementation.
- For Bulgaria CVD screening, consolidate Hubis/CPC monitoring data into a scalable pathway for high-risk patients.

8. Contact information

Key contacts for further information or questions

DIGI4Care Pilot 1 partner teams in Bulgaria, Hungary, Romania and Slovakia;

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