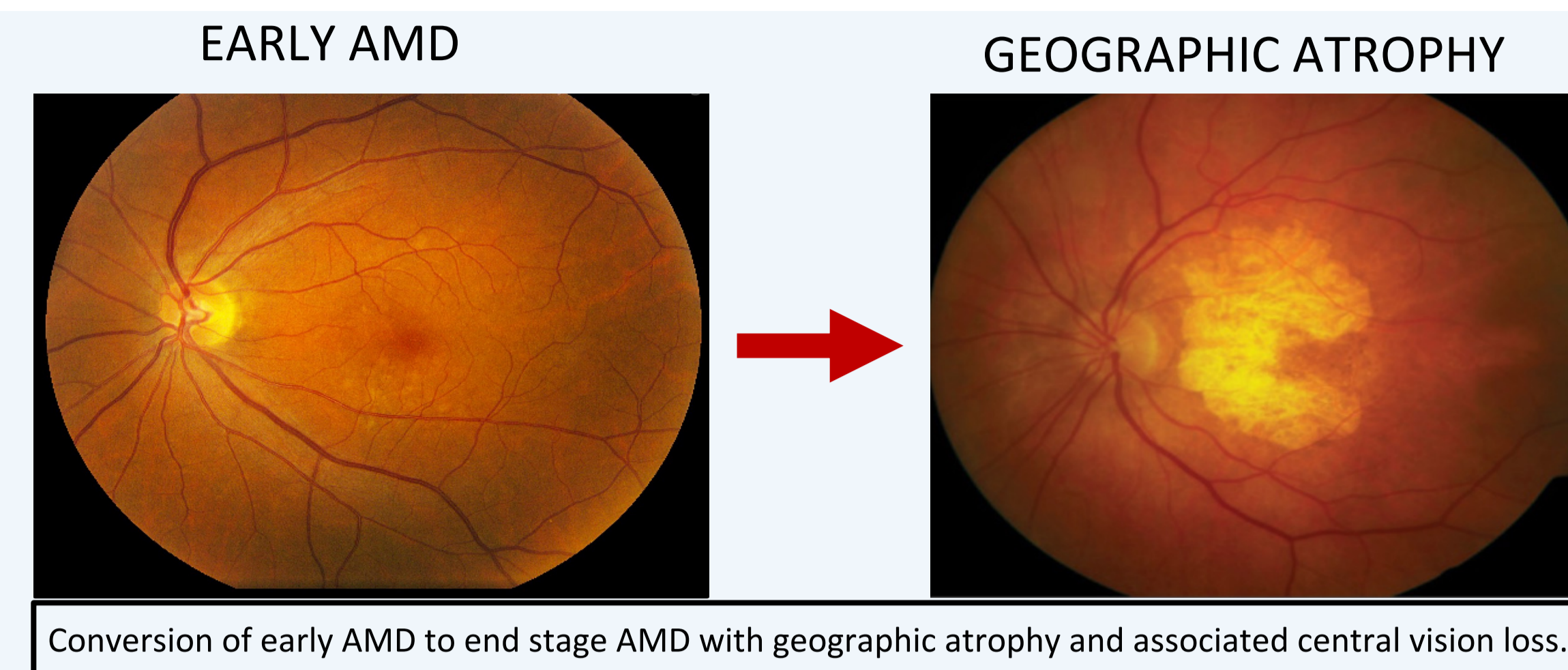# AI-powered Geographic Atrophy model (GAIA) for screening for clinical trial eligibility and as a clinical decision support tool

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Problem

- Geographic Atrophy (GA) is the most common form of late stage age-related macular degeneration (AMD), which is the leading cause of vision loss in the world.
- There are now 2 FDA approved treatments and several phase 3 trials underway for future therapies, meaning there will be NHS treatment availability incoming shortly.
- For treatment we need to (A) identify eligible patients and (B) monitor the efficacy of the treatment. This requires analysing large volumes of ocular imaging data (optical coherence tomography) to look for specific features of GA. This task normally requires expert review on a very small scale by expert ophthalmologists.

EARLY AMD → GEOGRAPHIC ATROPHY

Conversion of early AMD to end stage AMD with geographic atrophy and associated central vision loss.
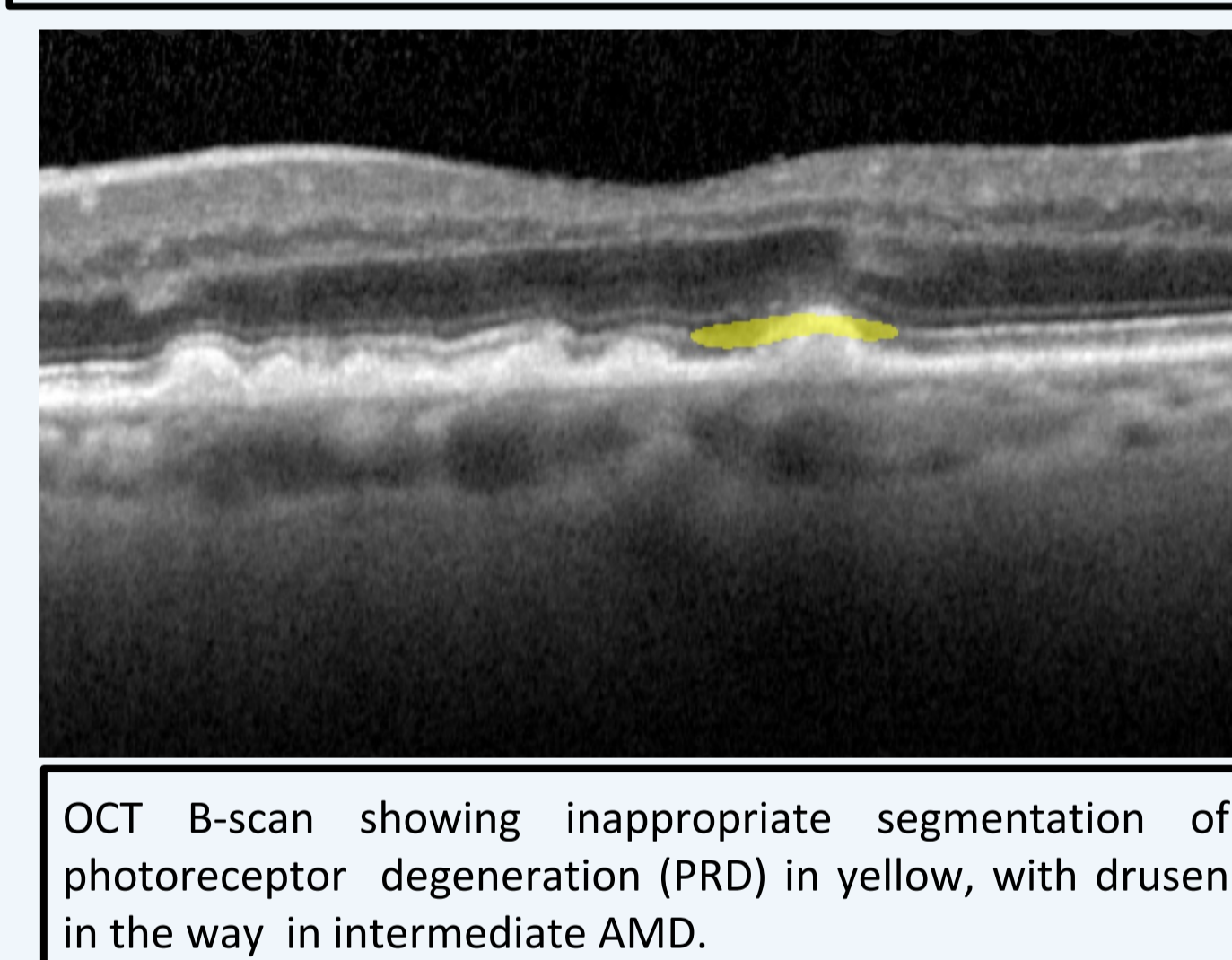
Solution

- We are trying to automate the process of identifying and monitoring treatment efficacy via the development of our novel NHS-owned in-house AI algorithm. We would look to deploy this at scale in the NHS and across the world.

- To begin with this GA AI algorithm (GAIA) model needs to be validated, deployed and monitored on large clinical trial and real-world datasets. Initial deployment will be aimed at understanding the impact of new treatments for dry macular degeneration on service provision.

- The equivalent treatments for wet macular degeneration (which became available in the early 2000s) currently cost the NHS around £500m per year (drug costs alone), and we expect that dry AMD treatments could be of a similar magnitude.

- The algorithm has been validated in a research setting, and we have received guidance from the MHRA that we can now proceed to deployment for the purposes of service delivery planning. From project initiation, we will plan for deployment as a clinical decision support tool.
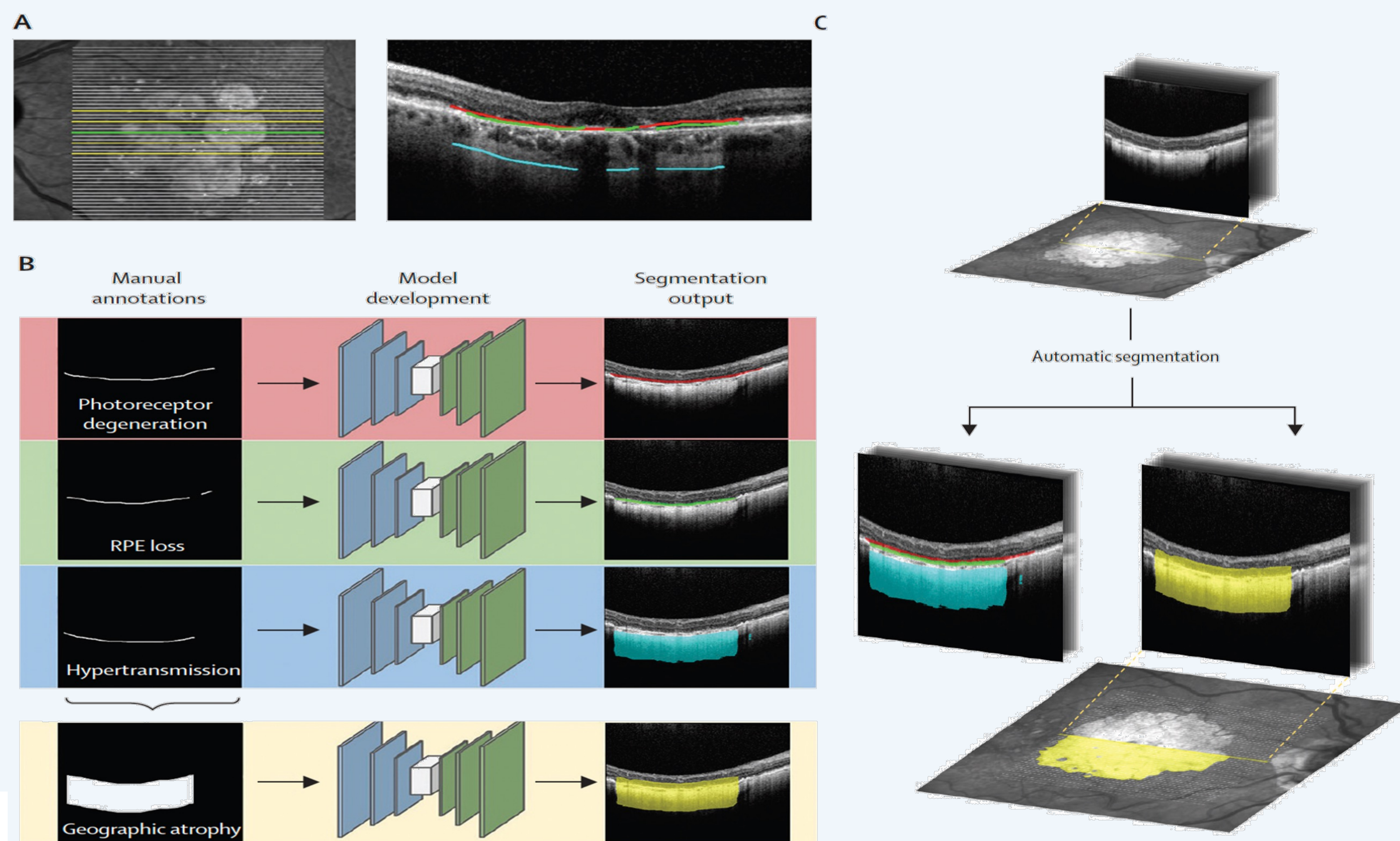
After training on manual annotations, GAIA is able to automatically segment all aspects of GA in an OCT volume (per 2D B-scan) (A & B); and when they all overlap confirms GA and quantifies the amount on a 3D volume (in yellow, C).

Progress

- We undertook the process for ISO 9001 certification for the reading centre.
- The steps involved were creating a quality management system (QMS) process, audit process, standard operating procedures (SOPs) and ability to undertake corrective actions for issues with delivery of service for the reading centre.
- Certification will help with running trials using the GAIA platform with pharmaceutical companies.
- The fellowship in clinical AI workshops helped me significantly with background knowledge to undertake this process, as well as working with the local Reading centre team.

CERTIFIED ISO 9001:2015 COMPANY

- We looked to improve model performance by training on intermediate AMD (cases of AMD with advanced wet or dry changes).
- Active learning was used to improved model performance.
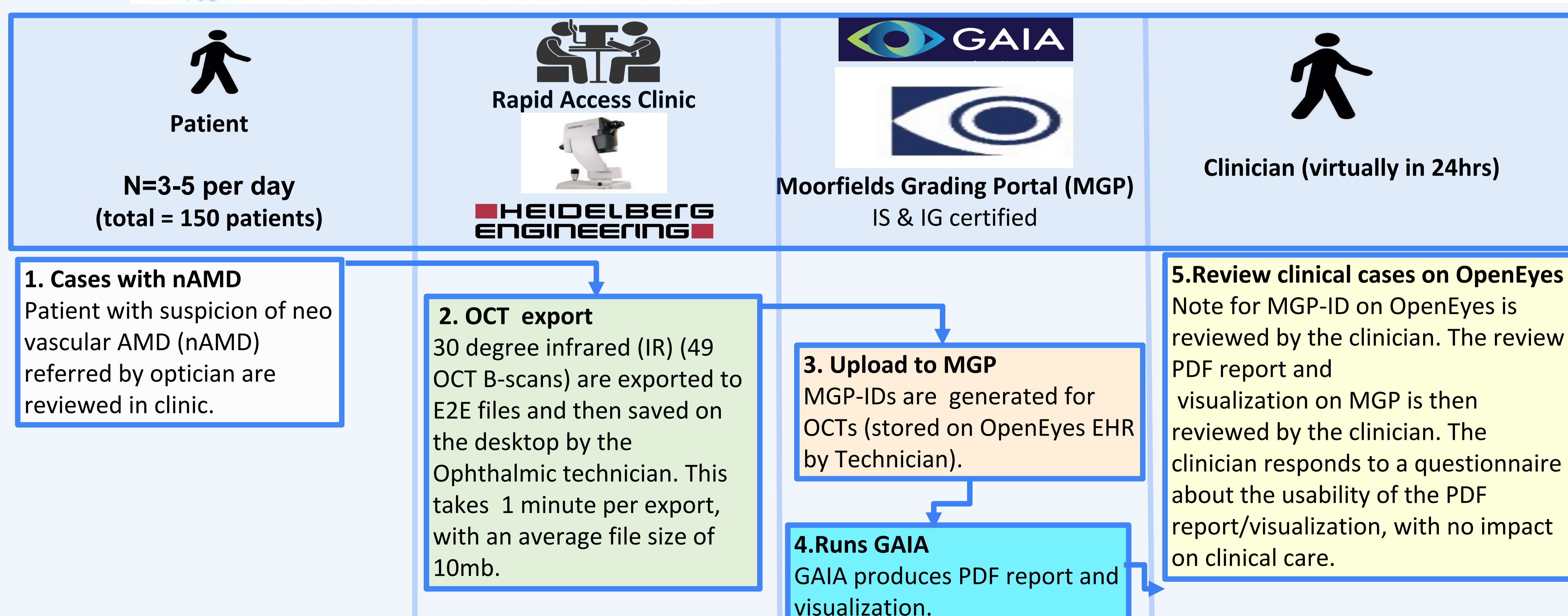- The clinicians, graders and data scientists helped to achieve this output to improve the model.

OCT B-scan showing inappropriate segmentation of photoreceptor degeneration (PRD) in yellow, with drusen in the way in intermediate AMD.

JULY 2023 ————————————————————————→ JULY 2024

Moorfields Eye Hospital NHS Foundation Trust

- Information governance and information security approval applications were made for the GAIA model and infrastructure of Moorfields Grading Portal (MGP) including DPIA in October 2023.
- Approvals have been received in June 2024 to proceed with shadow deployment of the model in clinic.
- Senior staff within the Reading Centre were significantly involved in helping to achieve this approval.

Next steps

- We plan to undertake shadow deployment of GAIA with service evaluation from July 2024-December 2024.
- We will be reviewing the usability of the system by staff (ophthalmic technicians and clinicians) in clinic at Moorfields.
- We may also use this data in the future to forecast for the number of future cases and treatment burden of GA to be reviewed at Moorfields going forward

Patient
N=3-5 per day
(total = 150 patients)

Rapid Access Clinic
HEIDELBERG ENGINEERING

GAIA
Moorfields Grading Portal (MGP)
IS & IG certified

Clinician (virtually in 24hrs)

1. Cases with nAMD
Patient with suspicion of neo vascular AMD (nAMD) referred by optician are reviewed in clinic.

2. OCT export
30 degree infrared (IR) (49 OCT B-scans) are exported to E2E files and then saved on the desktop by the Ophthalmic technician. This takes 1 minute per export, with an average file size of 10mb.

3. Upload to MGP
MGP-IDs are generated for OCTs (stored on OpenEyes EHR by Technician).

4. Runs GAIA
GAIA produces PDF report and visualization.

5. Review clinical cases on OpenEyes
Note for MGP-ID on OpenEyes is reviewed by the clinician. The review PDF report and visualization on MGP is then reviewed by the clinician. The clinician responds to a questionnaire about the usability of the PDF report/visualization, with no impact on clinical care.

Schematic for operational set up for shadow deployment showing the steps from image acquisition, upload to MGP, generation of report using GAIA and then visualisation by clinician.