

Antibody fragment



Diabetic Retinopathy. Current management and treatment protocols including national targets - 18 weeks and KPI DR3



NICK LEE

**Consultant Hillingdon & Western
Eye Hospitals.**



- **10 To ensure timely consultation for all screen-positive patients.**
 - R3 70% < 2 weeks - 6% & 0%
 - R2 70% < 13 weeks - 27% 62%
 - M1 70% < 13 weeks - 21% 63%
 - All other grades 100% < 18 weeks - 31% 60%

- **11 To ensure timely treatment of those listed by ophthalmologist (Laser)**
 - R3 90% < 2 weeks 0% 100%
 - M1 70% < 10 weeks 70% 100%

- **12.** To minimise overall delay between screening event and first laser treatment.

R3 70% <4 weeks 0% 0%

- 100% <6 weeks 33% 100%

- **15 To ensure timely re-screening**

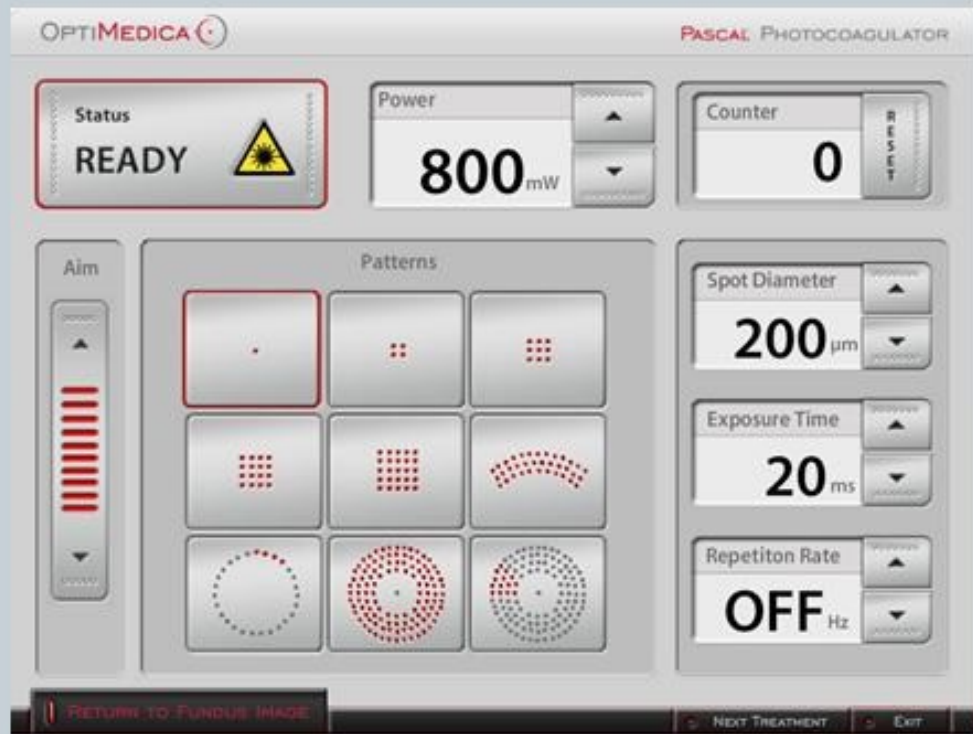
12 months 70% - 29%

15 months 95% - 80%

- **20.** To ensure timely biomicroscopy assessment of patients deemed unobtainable/raw ungradable or inadequate (unassessable)

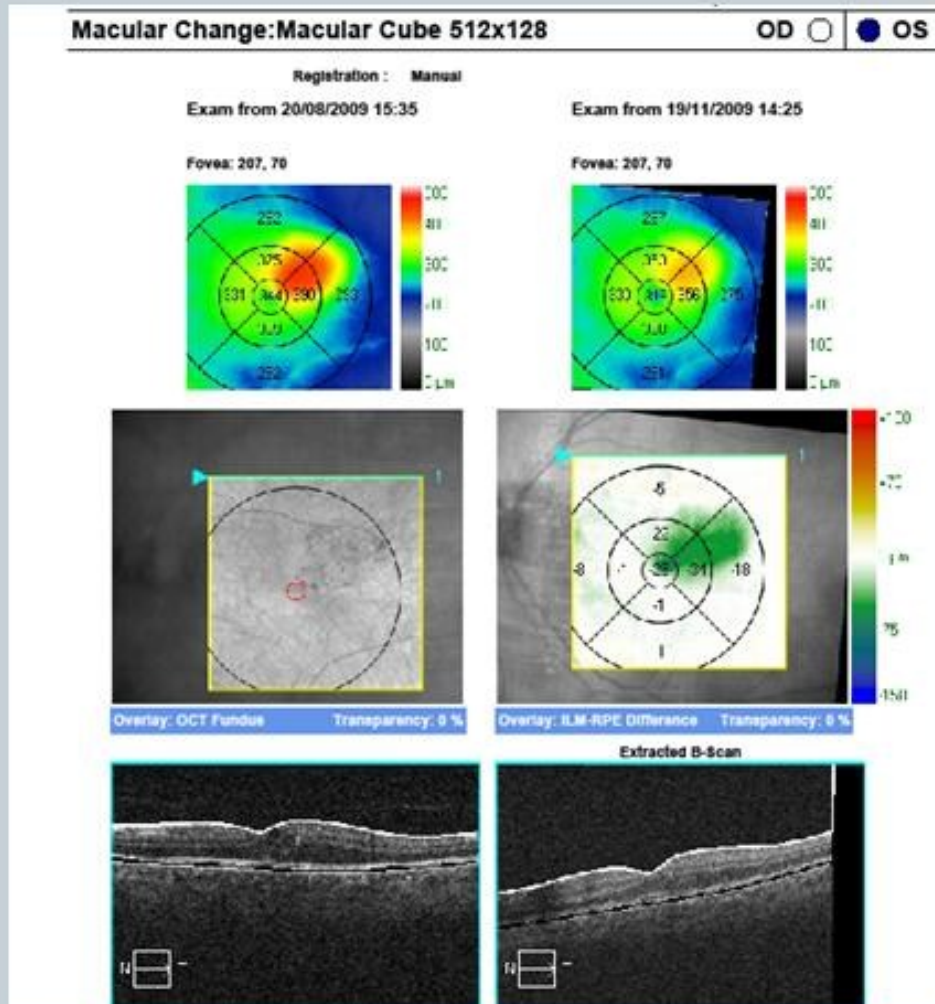
70% within 14 weeks 16% 23%

Treatment Pascal Laser



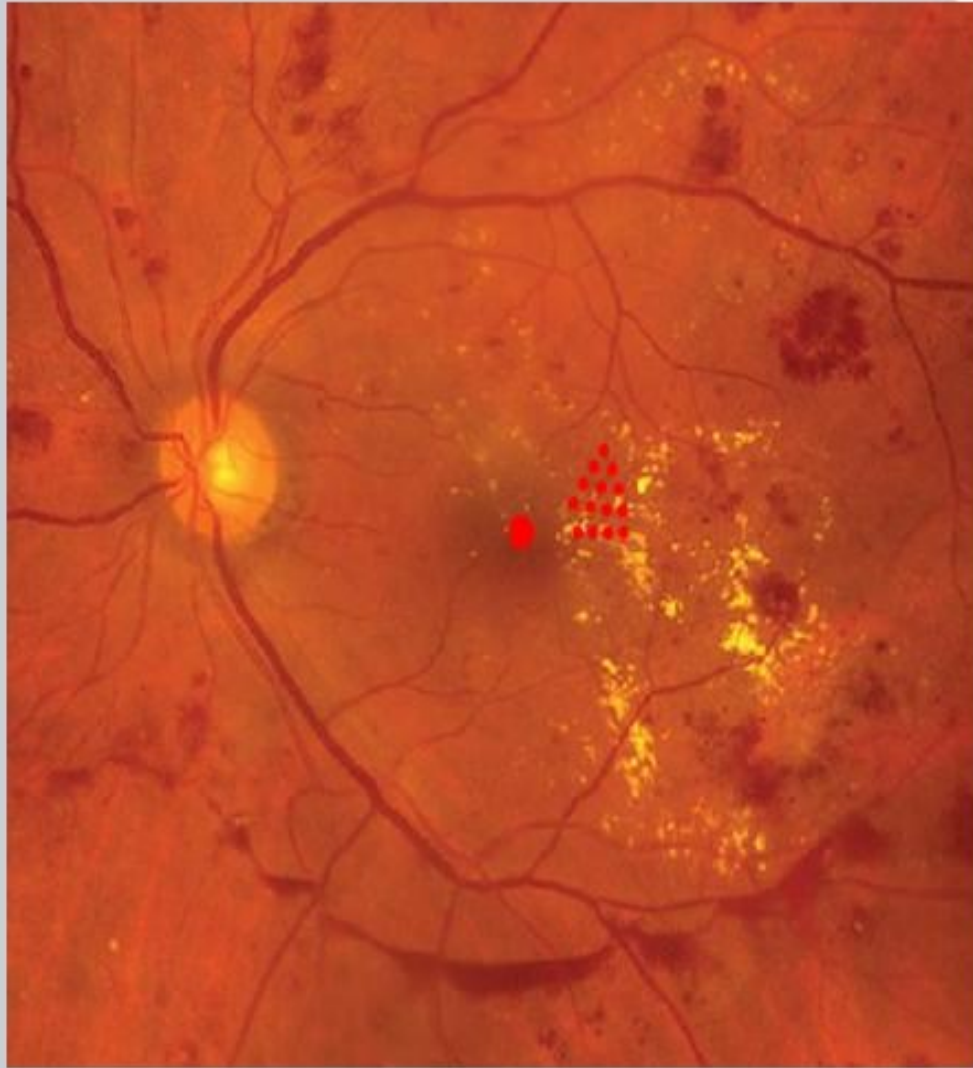
Optopol – Topcon Now supply The training Software. – Request.

Diabetic Laser - Pascal

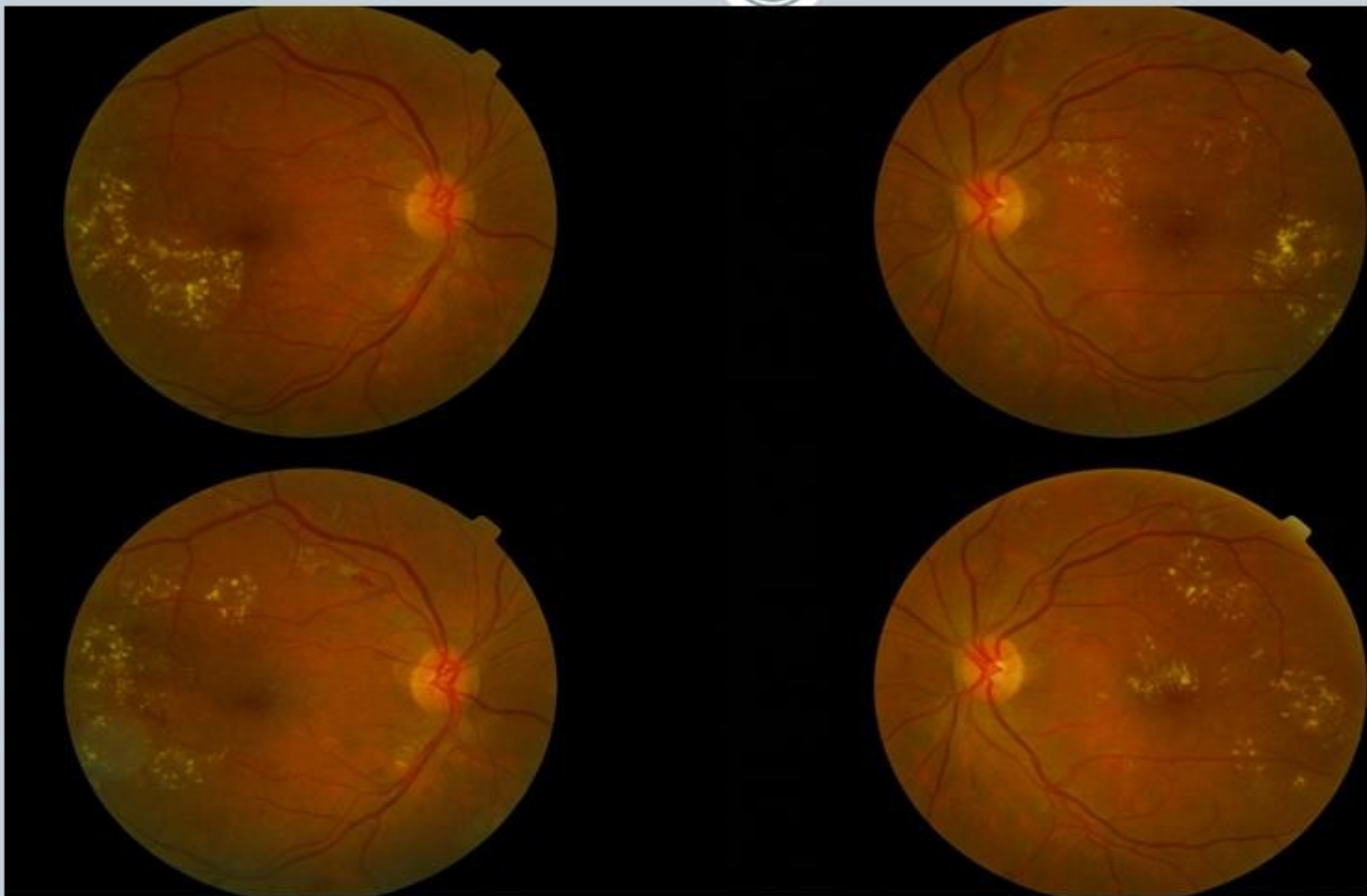


Remains gold Standard
Goes on working for 18 months

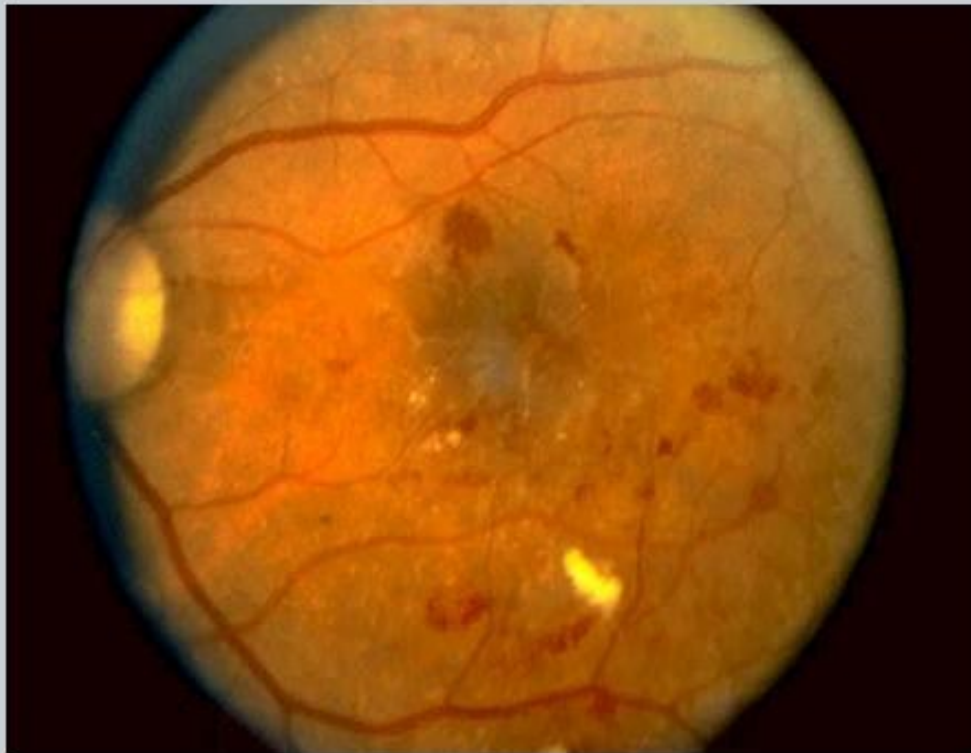
Pascal Treatment. 971 in 1 min!



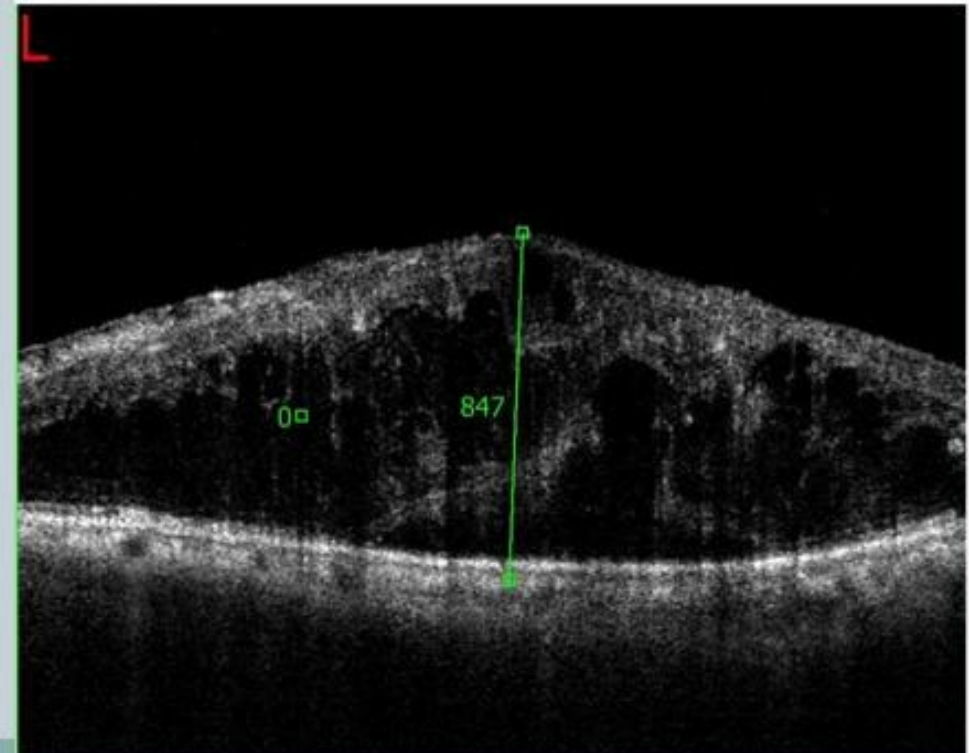
4 Up comparison After Laser



Foveal Diffuse DME??

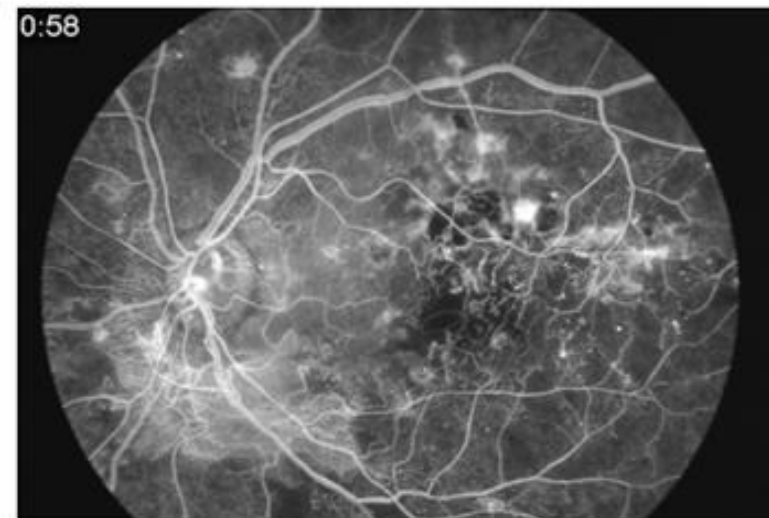


BEHARRY SONNY /Ref: 5049010 Doc: 1529-03-20
Examination date: 2008-08-12 11:13:17
SOCT Copernicus 8151-20.2/F



VEGF₁₆₅ in Diabetic Retinopathy

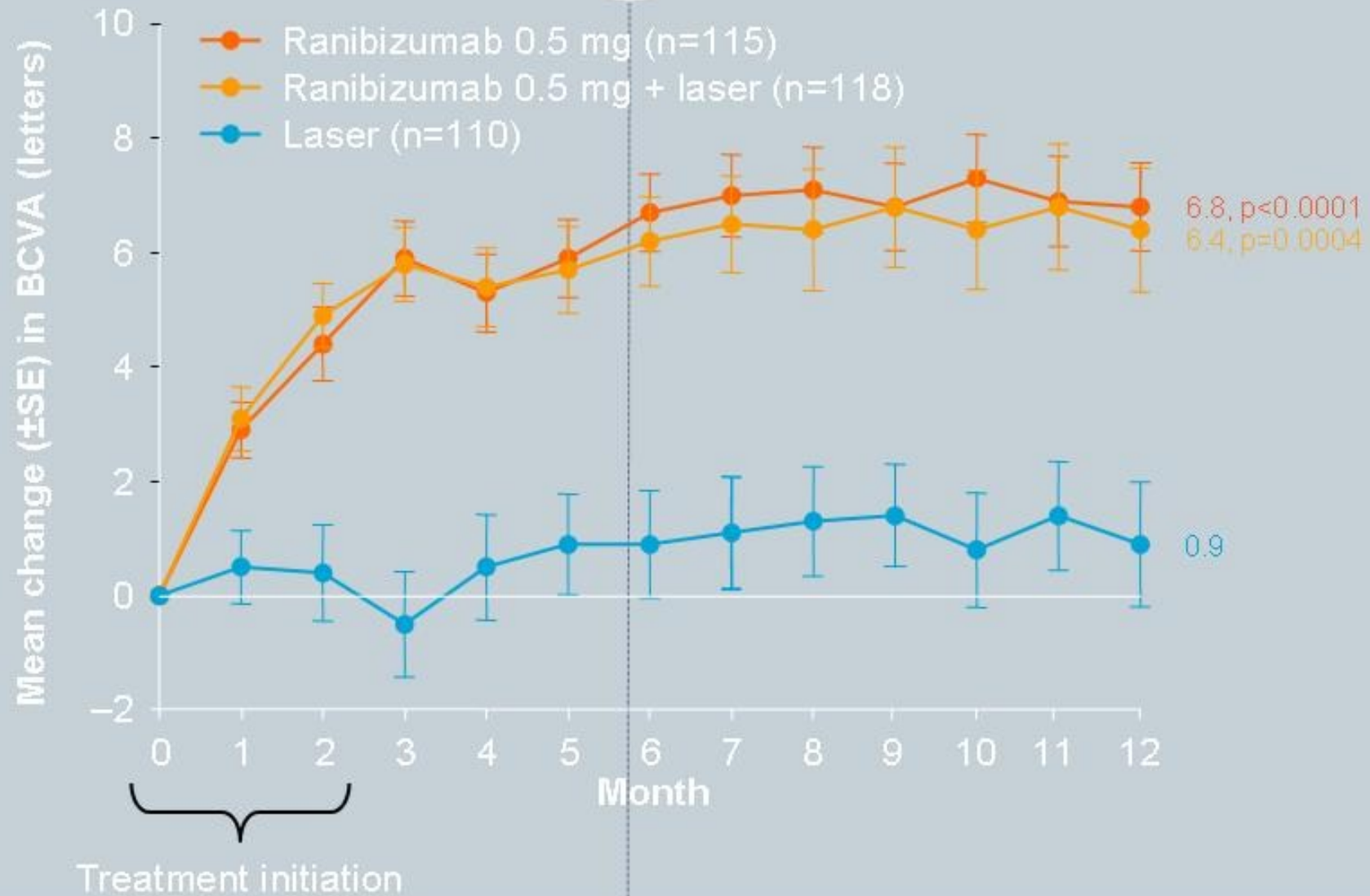
- Retinal VEGF₁₆₅ levels elevated in experimental diabetes
- Increased VEGF₁₆₅ levels found in vitreous of eyes with proliferative DR
- DR patients have higher VEGF₁₆₅ levels in the aqueous
- Higher than AMD!



Clinical trials with ranibizumab in patients with visual impairment due to DME

- Several clinical trials have now provided evidence of the efficacy of ranibizumab in patients with visual impairment due to DME
 - **RESOLVE:** ranibizumab monotherapy provided superior improvements in mean average BCVA and CRT compared with sham injection
 - **RESTORE:** ranibizumab as monotherapy or adjunctive to laser provided superior improvements in mean average BCVA and CRT compared with laser monotherapy
 - **DRCR.net:** ranibizumab treatment in combination with prompt or deferred laser therapy provided superior improvements in BCVA and CRT compared with focal/grid laser treatment alone

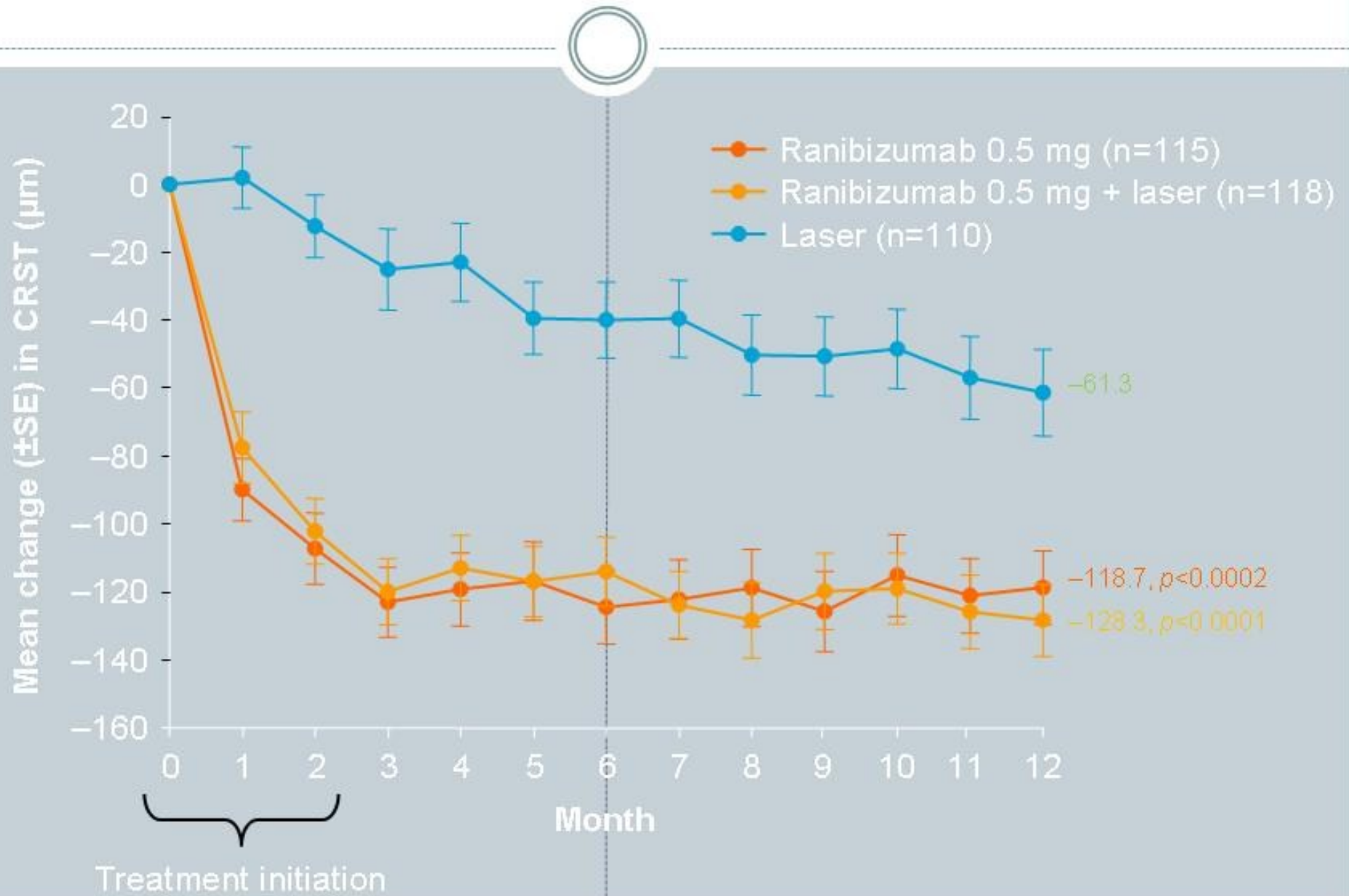
Restore - Mean BCVA



The Liverpool Declaration

- St. Vincent Declaration Liverpool 1989 & 1990
- November 2005 a conference took place to review progress joint meeting between diabetologists and ophthalmologists from each English screening programme
- ***European countries should:***
- Reduce the risk of visual impairment due to diabetic retinopathy by 2010 by:
- systematic programmes of screening reaching at least 80% of the population with diabetes
- using trained professionals and personnel
- universal access to laser therapy

Restore Mean CRT

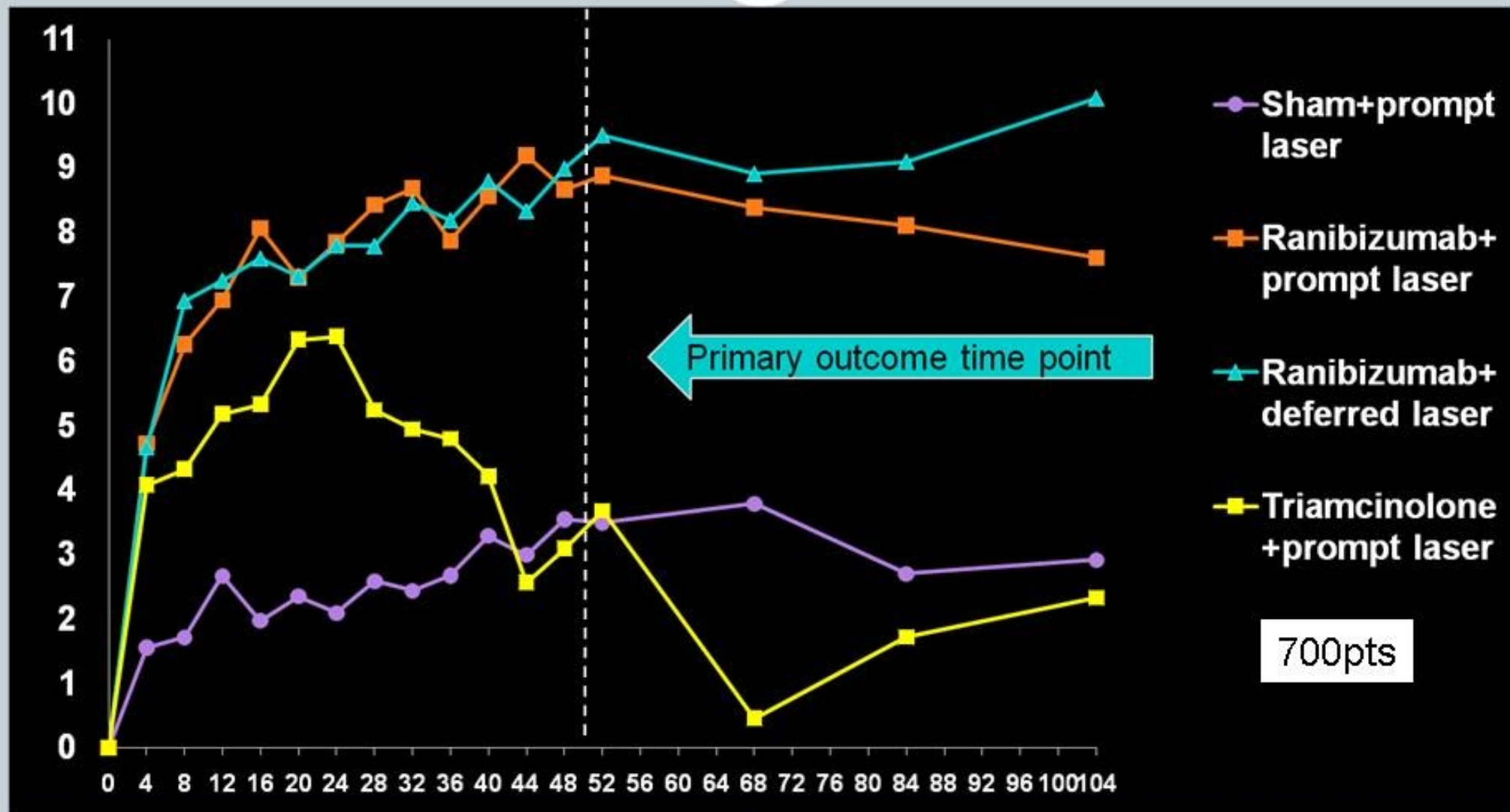


Adverse events potentially related to systemic VEGF inhibition

Preferred term (safety set)	Ranibizumab 0.5 mg N=115 n (%)	Ranibizumab 0.5 mg + laser N=120 n (%)	Laser N=110 n (%)
Total	14 (12.2)	7 (5.8)	11 (10.0)
Arterial thromboembolic	4 (3.5)	4 (3.3)	3 (2.7)
Arterial thrombosis limb	1	0	0
Carotid artery stenosis	1	1	1
Cerebral artery embolism	1	0	0
Cerebrovascular accident	1	0	0
Cerebrovascular disorder	0	1	0
Coronary artery occlusion	0	1	1
Myocardial infarction	1	1	0
Peripheral arterial occlusive disease	1	0	1
Vertebrobasilar insufficiency	0	1	0
Venous thromboembolic events	2 (1.7)	0 (0.0)	2 (1.8)
Hypertension	9 (7.8)	6 (5.0)	9 (8.2)
Non-ocular haemorrhage	1 (0.9)	0	1 (0.9)
Epistaxis	1 (0.9)	0	1 (0.9)
Proteinuria	1 (0.9)	1 (0.8)	0

DRCR.net Lucentis

Mean Change in Visual Acuity at Follow-up Visits



* Values that were ± 30 letters were assigned a value of 30

P-values for difference in mean change in visual acuity from sham+prompt laser at the 52-week visit:

ranibizumab+prompt laser < 0.001; ranibizumab+deferred laser < 0.001; and triamcinolone+prompt laser = 0.34

Avastin (Bevacizumab) for DIABETIC MACULAR OEDEMA

- Pan American Collaborative Retina Study group 24 month results
- Retrospective study, Interventional study
- 115 Patients
- Injections average 5.8 (1 to 15)
- Vision improved 0.92 to 0.76 (8 letters)
- OCT decreased from 466 to 286 microns

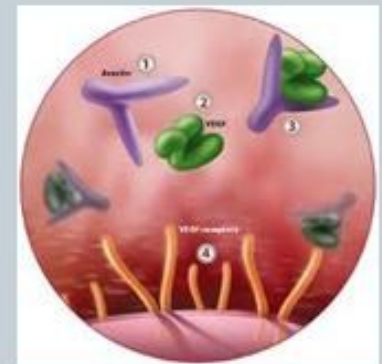
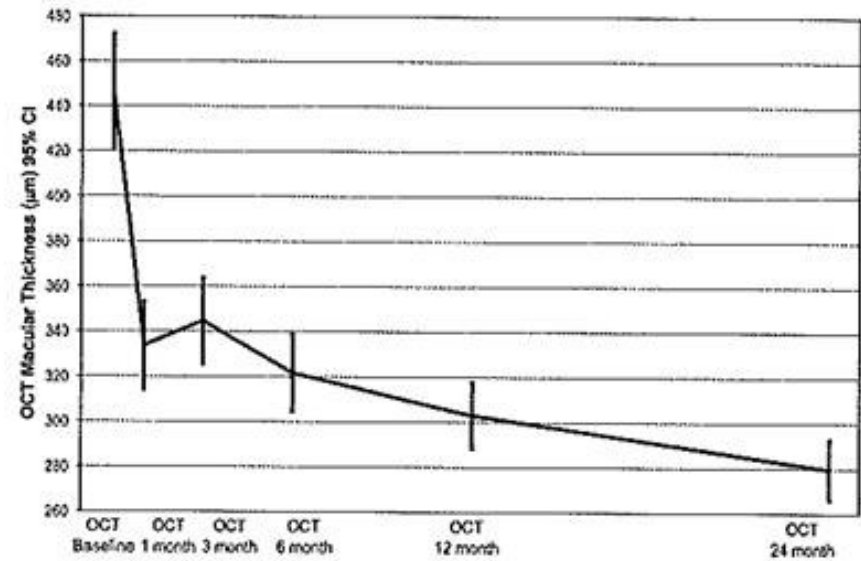
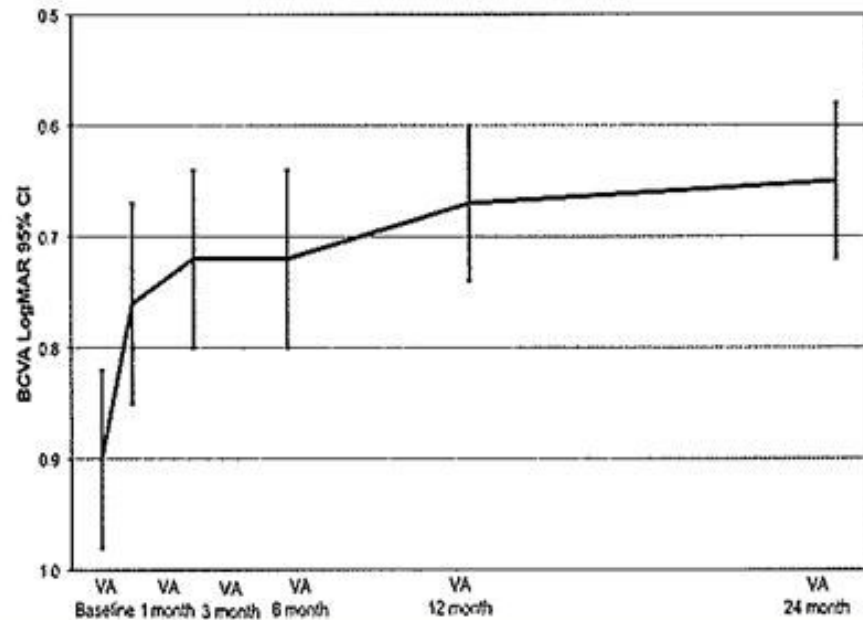


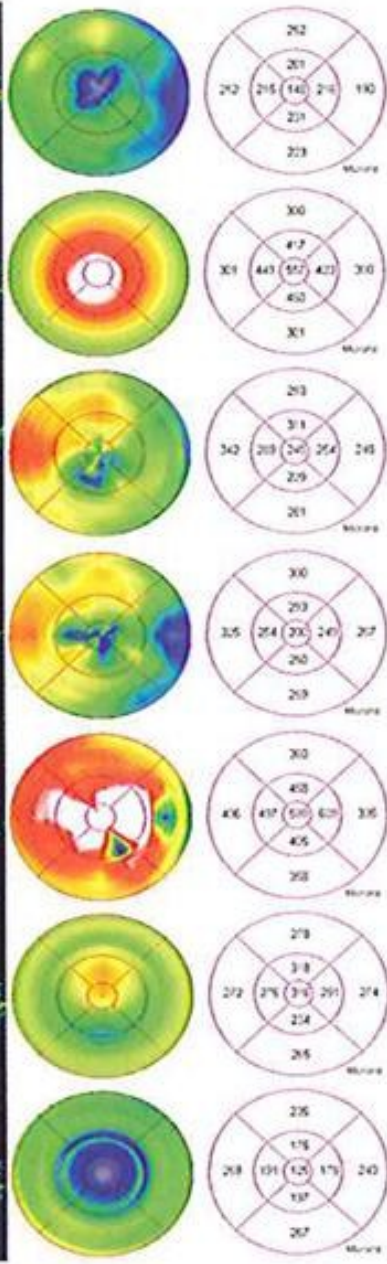
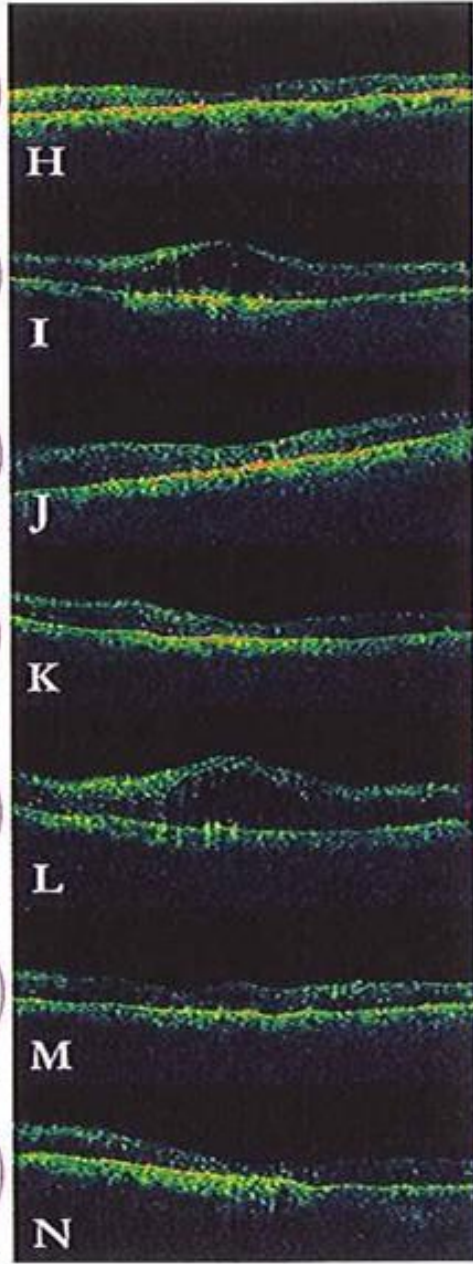
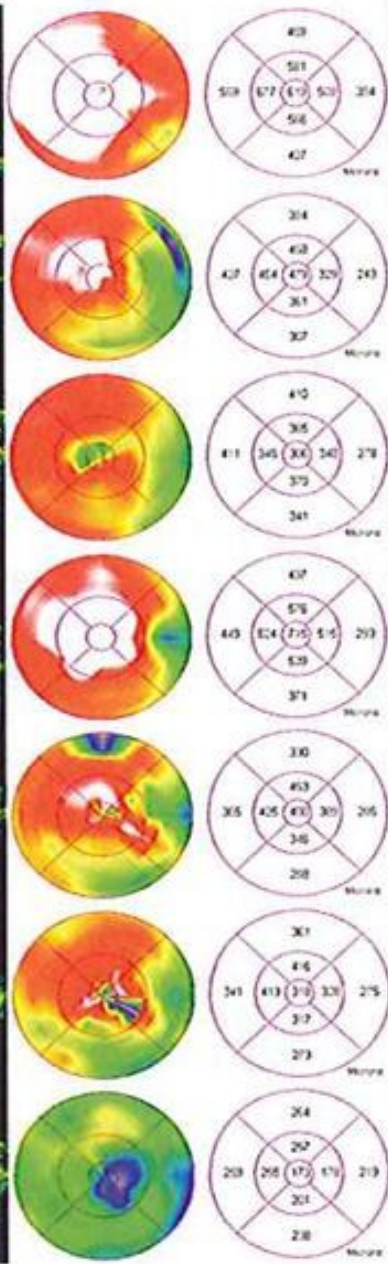
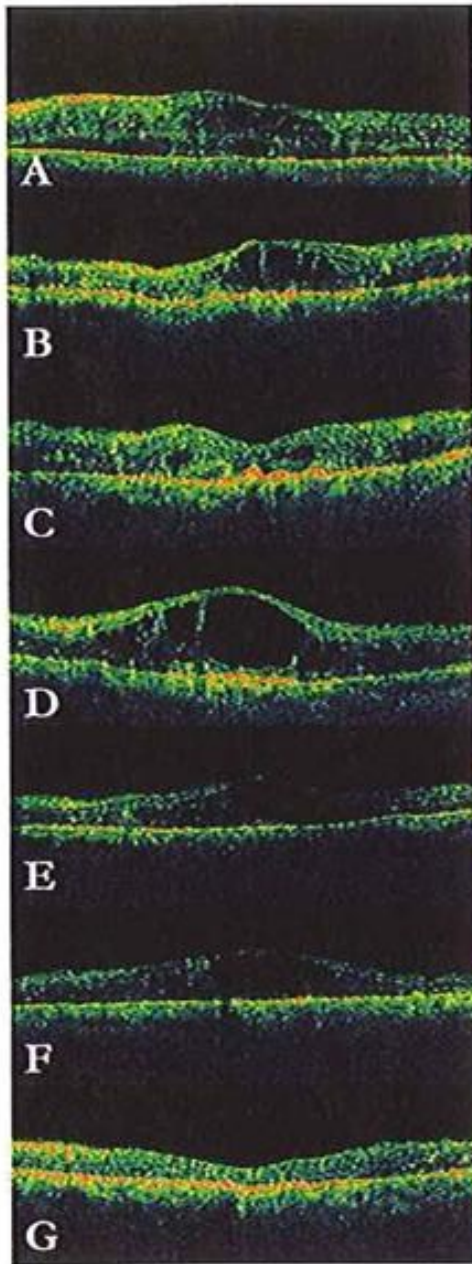
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Avastin (Bevacizumab) Results





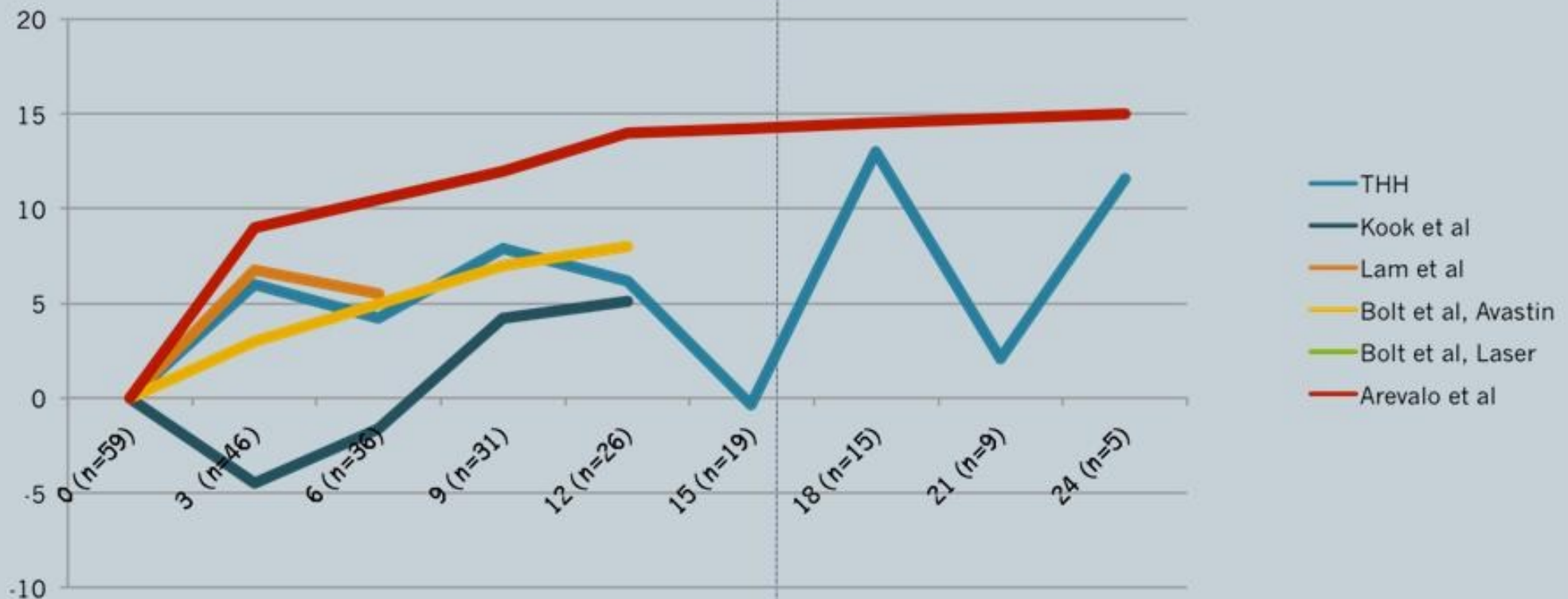
Hillingdon Audit DME - Avastin



- Approved 2007 by Hospital/PCT
- Supported by Physicians
- 90 patients identified with DM who have had intravitreal injections with Avastin
- All had previous laser – Further Deferred laser allowed
- 59 patients id'd with adequate data recorded
 - Missing VA
 - Not enough time post injection
 - Rx for PDR



Chart of BCVA comparison to Avastin trials



Comparison Outcomes Letter Improvement

	VA @ 12m	No Inj	Laser arm	No pts
Resolve	10.3	10	-	150
DRCR Lucentis	9	9	6	700
Restore	6.8	7	5.9	315
Read	6.5	6	7.6	126
Macugen	6.1	8	-	260
Pan American Collaborative Retina Study Avastin	8	5.8	-	115
Hillingdon Avastin	6	5	-	69

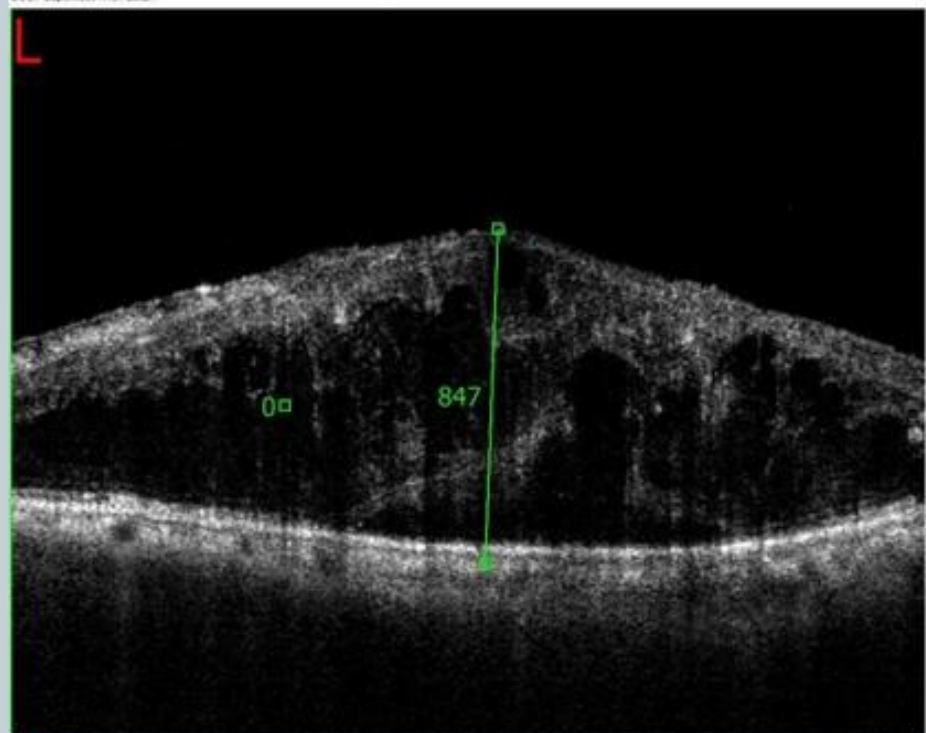
82 Yr Male Poor Vision 1.3



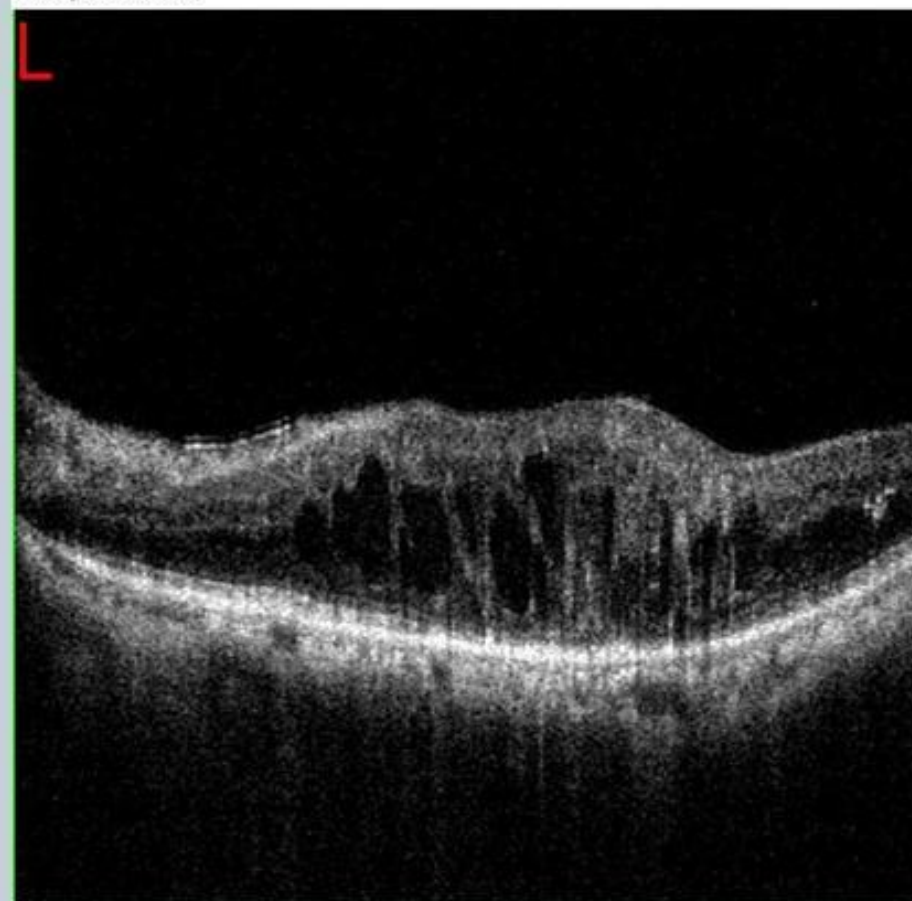
6/09

12/08

BEHARRY SONNY (Ref: 02490310 Dob: 1929-03-28)
Examination date: 2008-09-12 11:13:17
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BEHARRY SONNY (Ref: 02490310 Dob: 1929-03-28)
Examination date: 2009-06-22 15:06:18
SOCT Copernicus #151-28.2/F



Systemic risk factor management targets for patients with diabetes

First Retinal Linked to GP surgeries

- **HbA_{1c}**
- Patient and physician should jointly agree an individualised target:
- IFCC-HbA_{1c} (mmol/mol) = (HbA_{1c} % - 2.15) x 10.929
- or
- Old HbA_{1c} = (IFCC/10.929) + 2.15
- <6.5% is the aspiration = 48
- <7.0 or <8.0 may be acceptable 53 - 64
- a % reduction over a specified time is an alternative approach
- Team working as recommended in DAFNE should be in place.
- **Blood Pressure (BP)**
- Patients with diabetic retinopathy should have a target BP of 130/80
- In the presence of co-existing nephropathy this should be lower.
- **Lipids**
- Target lipid values
- TC < 5.0 mmol/l
- LDL-c < 3.0 mmol/l
- TG < 2.3
- Commence statins in:
- patients with diabetes aged 40 or over
- patients with diabetic retinopathy aged 19 or over

Continued improvement !!!

DOB: 28/03/1929
 Gender: Other
 Doctor:

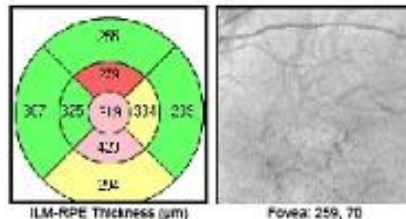
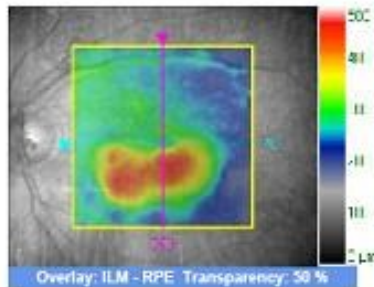
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 Exam Time: 11:10
 Technician: Hillingdon Hospital Staff,
 Signal Strength: 6/10

The Lee Medical Practice

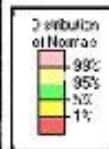
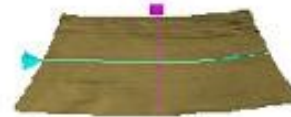
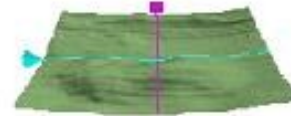
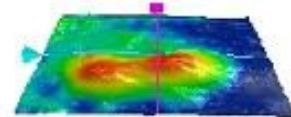
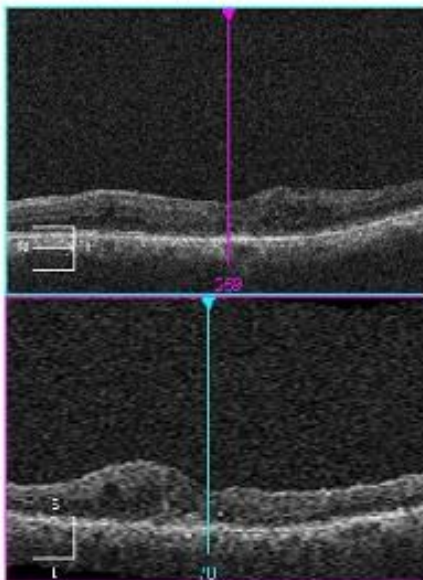
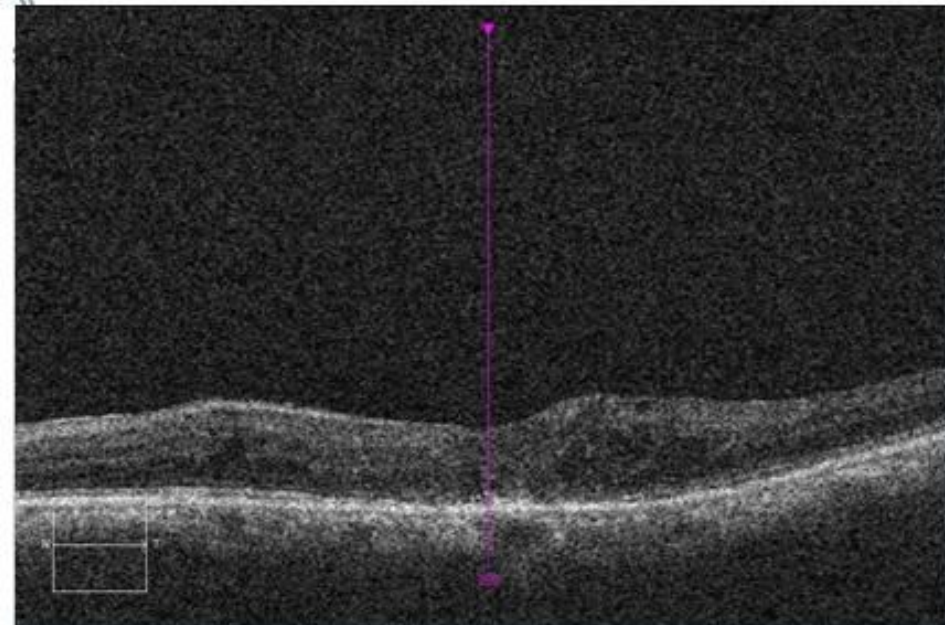


Macula Thickness : Macular Cube 512x128

OD OS



Fovea: 259, 70



	Central Subfield Thickness (µm)	Cube Volume (mm³)	Cube Average Thickness (µm)
ILM - RPE	319	10.1	281

- Vision improved from 1.3 to 1.06 12 letters
- Patient noticed improvement
- 7 injections

Comments
 Analysis Altered: 10/11/2009 11:14

Doctor's Signature

K9
 SW Ver: 4.0.1.3
 Copyright 2009
 Carl Zeiss Medtec, Inc
 All Rights Reserved

3D improvement

- Previous grids/laser
- Vision 6/18
- 3 Avastin (Bevacizumab) injections
- To continue
- Delighted pt

Macular Change: Macular Cube 512x128 OD OS

Registration : Automatic

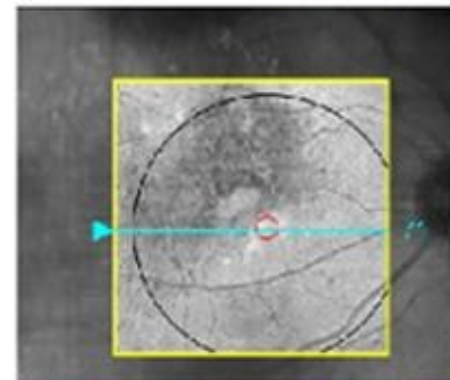
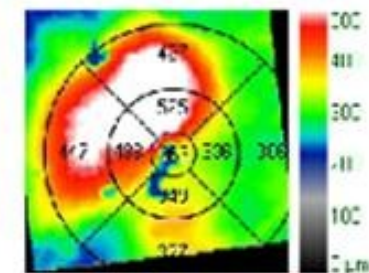
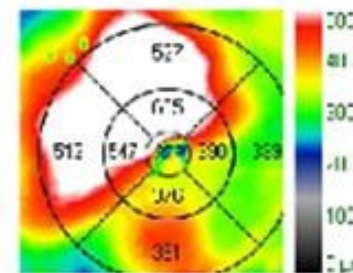
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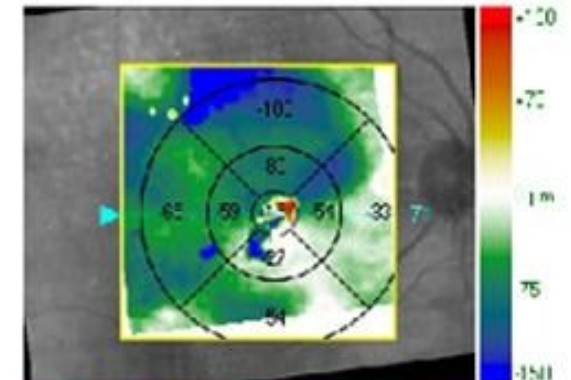
Exam from 19/11/2009 12:34

Fovea: 290, 70

Fovea: 290, 70

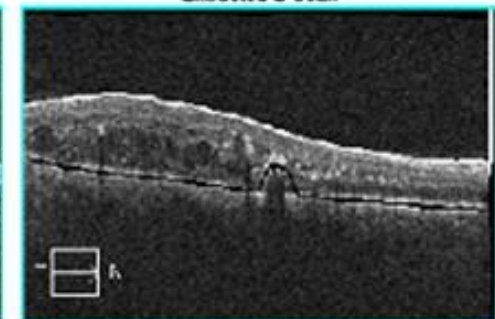


Overlay: OCT Fundus Transparency: 0 %



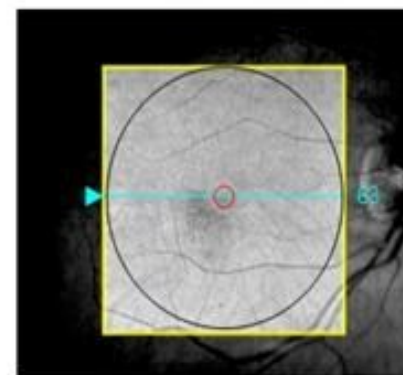
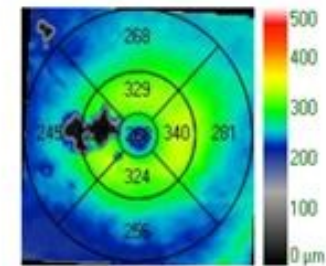
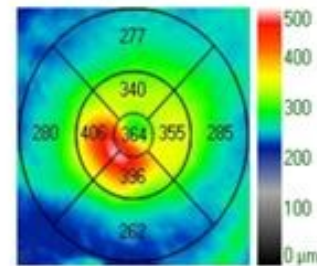
Overlay: ILM-RPE Difference Transparency: 0 %

Extracted B-Scan

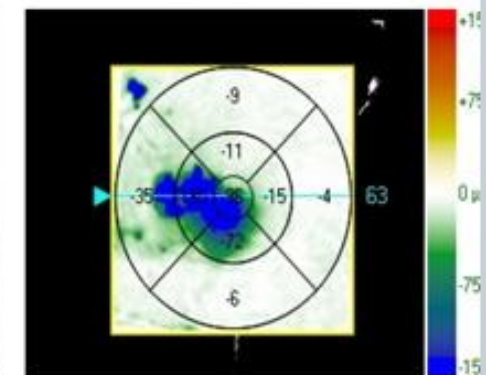


Lucentis improvement

- Vision pre injection 0.24
- Post injection 0.12
- Complete resolution of CMO.

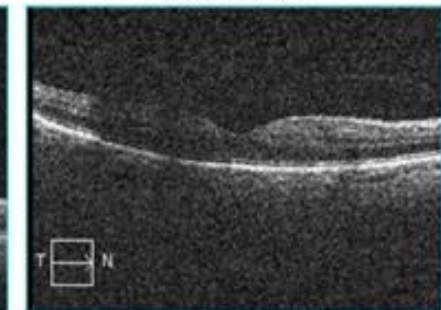
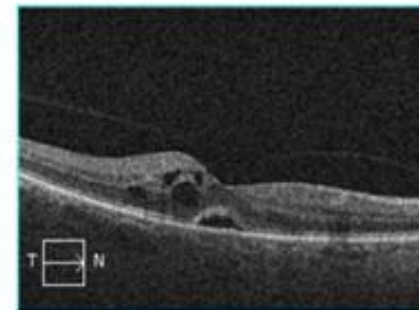


Overlay: OCT Fundus Transparency: 0 %



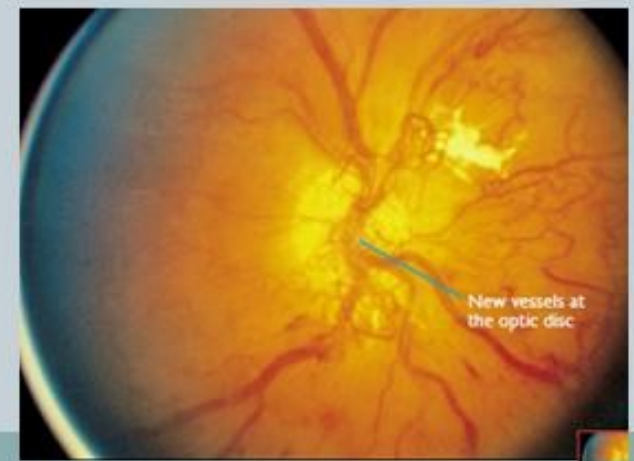
Overlay: ILM-RPE Difference Transparency: 0 %

Extracted B-Scan



What about Persistent NVE?

- PRP – Very effective. 1st Line
- Avastin /Lucentis injections?
 - Study Schmidinger Vienne 2009 Acta Ophthalmol
 - 11 eyes of 10 eyes Persistent NVE
 - 73% Showed complete resolution in one month
 - Vision improved from 59 to 70 letters
- Concerns of tractional detachments
- Definitive trials required
- Vitreous Haemorrhages?
- Use for persistent new vessels after full PRP.



Summary



- Focal/Circinate Lesions – Laser – Gold Standard
- Diffuse diabetic macular oedema / Central
 - Lucentis /Avastin
 - Fundus fluorescein angiography
 - ✦ Pascal Grids + Target micro-aneurysms
 - ✦ Have FFA displayed with laser
 - (Trimacinolone)
 - Doctor/Patient partnership important – Retention of patients

Future

North East Treatment Advisory Group

- Nice Application Lucentis DME Appeal 4/10/2011
- Slow release preparations – Genetech Commissioned
- NVE/NVD Trials
- Other on going trials in DME
 - ✦ Reveal – Asia Pacific clone of Restore
 - ✦ Ride & Rise 0.3 Vs 0.5 Vs Sham
 - ✦ Relation Germany Including Proliferative Disease
 - ✦ Retain Europe Stability treat and extend
- Automated Laser guided by FFA?.



Reducing the risk of sight loss
amongst people with diabetes



National Screening Programme for
Diabetic Retinopathy

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National Electronic
Library for Health
Diabetes



site developed by Netsima Ltd >

Welcome to the English National Screening Programme for Diabetic Retinopathy (ENSPDR)

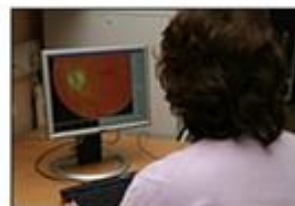
The aim of the programme is to reduce the risk of sight loss amongst people with diabetes, by the prompt identification and effective treatment if necessary of sight threatening diabetic retinopathy, at the appropriate stage during the disease process.

Systematic screening involves digital photography of the retina followed by a two- or three- stage image grading process to identify the changes of sight-threatening diabetic retinopathy in the retina.

This web site has been developed to be of use to the public and health professionals. It has some features to make finding content and keeping up to date with changes much easier. If you are new to this site please visit the [Site Features >](#) section.



The latest edition of the ENSPDR newsletter is now available: [ENSPDR newsletter](#)



02 October 2011

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Important Documents

Documents for all readers

- [Diabetic Retinopathy Facts >](#)
- [Preparing for Laser Treatment >](#)
- [Screening in pregnancy >](#)

Documents for Health Professionals

- [Serious Incident Handbook >](#)
- [Failsafe document >](#)
- [DRS Workbook >](#)
- [EQA Visit Guidelines >](#)
- [QA Standards 7 >](#)
- [Enriched grading form >](#)
- [SLB guidance >](#)

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Recommended Links

[NHS Diabetes >](#)
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UK National Screening Committee

Key Performance Indicators for Screening, 2011-12 KPi's

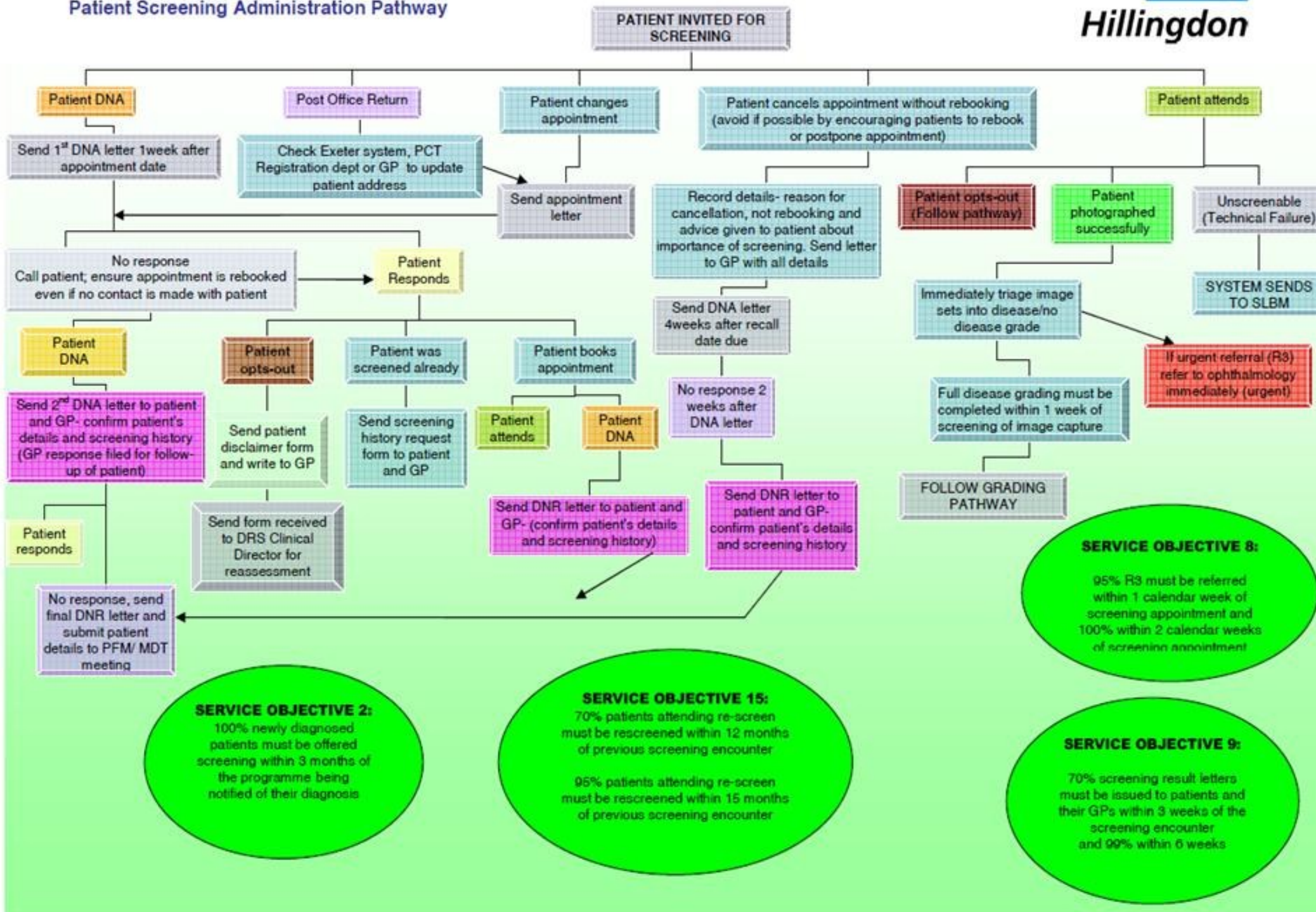


- **DR1 Diabetic retinopathy – uptake of digital screening encounter**
- **DR2 Diabetic retinopathy – results issued within 3 weeks of screening**
- **DR3 Diabetic retinopathy – timely consultation for R3 screen positive**

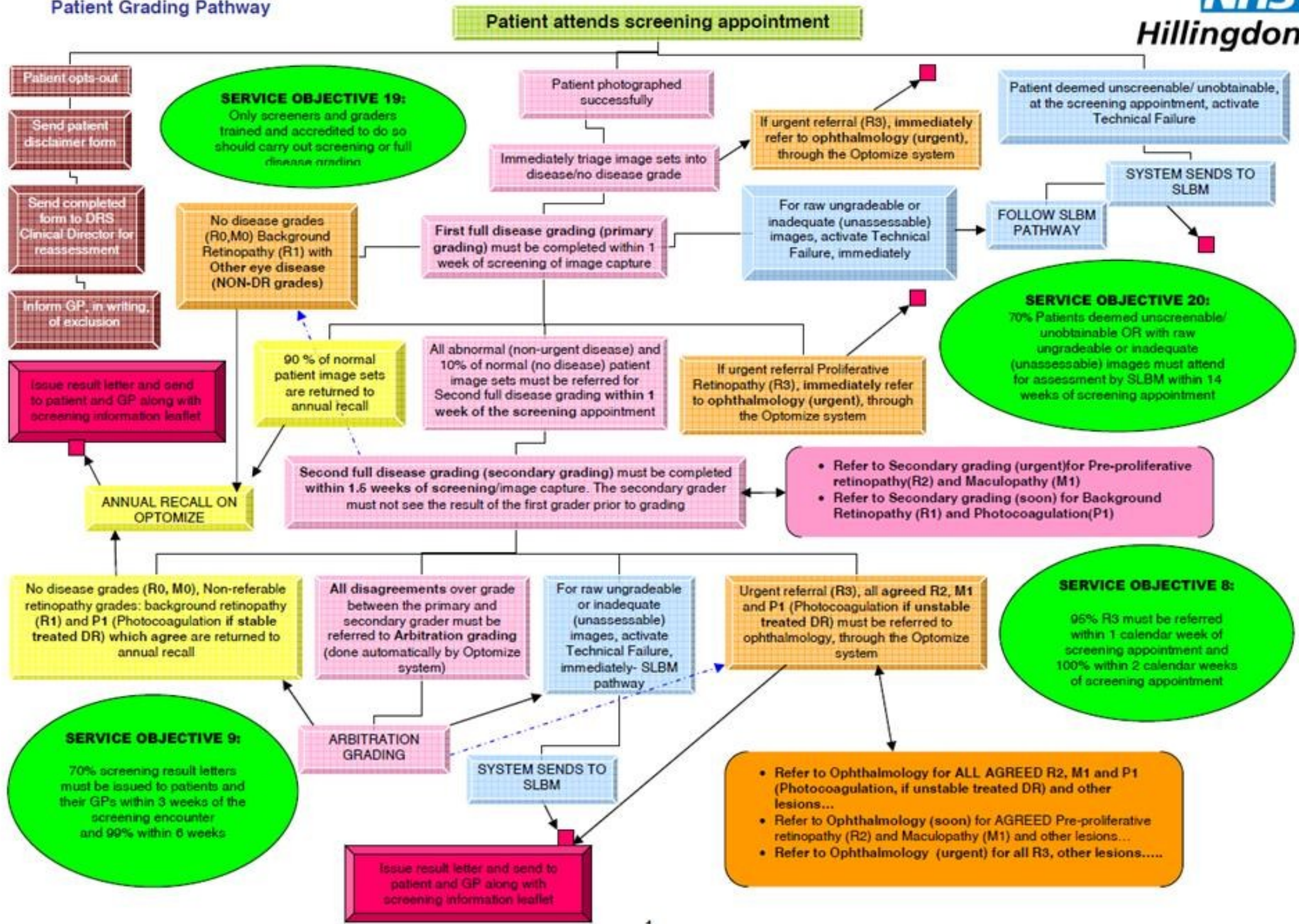
DRSS Programme

- KCW – First Retinal
 - 434,000 Population
 - 15,000 With diabetes to be screened annually.
- Hillingdon – Medical imaging
 - 350,000
 - 12,0000 with diabetes to be screened annually.
- Overseen by DRSS Programme Board
 - Quarterly meetings
 - Screening Company, PCT, Public Health Director, Hospital, Lead Clinicians, Diabetologists.

Patient Screening Administration Pathway



Patient Grading Pathway



KCW Service Objectives and Quality Assurance Standards 20

- **1** To reduce new blindness due to diabetic retinopathy. 10% - 40% reduction within 5 years of start of screening programme
- **2** To invite all eligible persons with known diabetes to attend for the DR screening test. 100%
- **4** To maximise the number of invited persons accepting the test. 60% (70%)
- **8** To ensure timely referral of patients with R3 60% (95%)