ICHOM

International Consortium for Health Outcomes Measurement

MACULAR DEGENERATION DATA COLLECTION REFERENCE GUIDE

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We are thrilled that you are interested in measuring outcomes for your macular degeneration patients according to ICHOM standards. It is our hope that this Reference Guide will facilitate the process of implementing our Standard Set and ensure collection of comparable data for global benchmarking and learning.

Introducing ICHOM and the Reference Guide

ICHOM brings together patient representatives, clinician leaders, and registry leaders from all over the world to develop Standard Sets, comprehensive yet parsimonious sets of outcomes and case-mix variables we recommend all providers track.

Each Standard Set focuses on patient-centered results, and provides an internationally-agreed upon method for measuring each of these outcomes. We do this because we believe that standardized outcomes measurement will open up new possibilities to compare performance globally, allow clinicians to learn from each other, and rapidly improve the care we provide our patients.

Our Standard Sets include initial conditions and risk factors to enable meaningful case-mix adjustment globally, ensuring that comparisons of outcomes will take into account the differences in patient populations across not just providers, but also countries and regions. We also include high-level treatment variables to allow stratification of outcomes by major treatment types. A comprehensive data dictionary, as well as scoring guides for patient-reported outcomes is included in the appendix.

Working Group Members for Macular Degeneration

The following individuals dedicated both time and expertise to develop the ICHOM Standard Set for Macular Degeneration in partnership with ICHOM, under the leadership of Dr. Mark Gillies, Professor of Clinical Ophthalmology & Eye Health at the University of Sydney Medical School.

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Supporting Organizations

The Macular Degeneration Standard Set is made possible only through the support of Wills Eye Hospital Philadelphia, Macular Society UK, Retina Suisse, Retina Society USA, Save Sight Institute Sydney, and St. Erik Eye Hospital Stockholm.

Thank you.

Conditions and Treatment Approaches Covered for Macular Degeneration

For Macular Degeneration, the following conditions and treatment approaches (or interventions) are covered by our Standard Set.

Conditions	**Neovascular Macular Degeneration** Neovascular Age Related Macular Degeneration | Polypoidal Choroidal Vasculopathy | Myopic Neovascular Macular Degeneration | Other Forms of Neovascular Macular Degeneration (includes Post-Traumatic, Inflammatory, Idiopathic, Macular Telangiectasia Type 2) **Non-Neovascular Age Related Macular Degeneration**
Treatment Approaches	Intravitreal anti-VEGF treatment | Other intravitreal treatment | Photodynamic therapy | Thermal laser photocoagulation | Retinal radiation therapy | Transpupillary thermotherapy | Retinal surgical treatment

ICHOM Standard Set for Macular Degeneration

Case-Mix Variables

Patient Population	Measure	Supporting Information	Timing	Data Source
Demographic Factors				
All patients	Age	Date of birth	Baseline	Clinical or administrative data
	Sex	Sex at birth		
	Ethnicity	Asian; Black; Hispanic; White; Mixed; Other		Patient-reported
	Smoking status	Smoking status (of cigarettes, cigars or tobacco)		
Baseline Functional Status				
All patients	Distance visual acuity	Distance visual acuity (best of uncorrected, corrected using glasses or contact lenses, or pinhole) in the affected eye	Baseline	Clinical
	Distance visual acuity in the fellow eye	Distance visual acuity (best of uncorrected, corrected using glasses or contact lenses, or pinhole) in the fellow eye		
Baseline Clinical Status				
All patients	Type of macular degeneration	Type of macular degeneration	Baseline; Each clinical visit to check for change	Clinical
	Geographic atrophy	Presence of geographic atrophy anywhere in the macular area that is not contiguous with the main lesion		
	Subretinal fibrosis	Presence of subretinal fibrosis anywhere in the macular area		
	Pigment epithelial detachment	Presence and type of pigment epithelial detachment anywhere in the macular area		
Associated Clinical History				
All patients	Ocular comorbidities	Ocular co-morbidities including retinal vascular disease, other macular pathology, glaucoma or optic neuropathy, amblyopia, or medial opacity in affected eye (multiple options possible)	Baseline; Prompt annually to check for change	Clinical
	Previous macular degeneration treatment	Previous macular degeneration treatment in study eye (multiple options possible) before the beginning of data reporting, including intravitreal anti-VEGF treatment, Intravitreal steroid, photodynamic therapy, thermal laser photocoagulation, retinal radiation therapy, transpupillary thermotherapy, retinal surgical treatment	Baseline	
Other Ocular Treatments				

All patients	Cataract surgery	Indicate if and when the patient received cataract surgery	Each clinical visit to check for change	Clinical
	YAG laser capsulotomy	Indicate if and when the patient received YAG laser capsulotomy		
	Retinal laser	Indicate if and when the patient received retinal laser therapy		
	Vitrectomy	Indicate if and when the patient received vitrectomy		
	Corneal surgery	Indicate if and when the patient received corneal surgery		

Treatment Approaches

Patient Population	Measure	Supporting Information	Timing	Data Source
All patients	Intravitreal anti-VEGF treatment	e.g. Ranibizumab (Lucentis); Bevacizumab (Avastin); Pegaptanib (Macugen); Aflibercept (VEGF-trap/Eylea)	Each clinical visit	Clinical
	Intravitreal steroid	N/A		
	Photodynamic therapy	N/A		
	Thermal laser photocoagulation	N/A		
	Retinal radiation therapy	N/A		
	Transpupillary thermotherapy	N/A		
	Retinal surgical treatment	N/A		

ICHOM Standard Set for Macular Degeneration

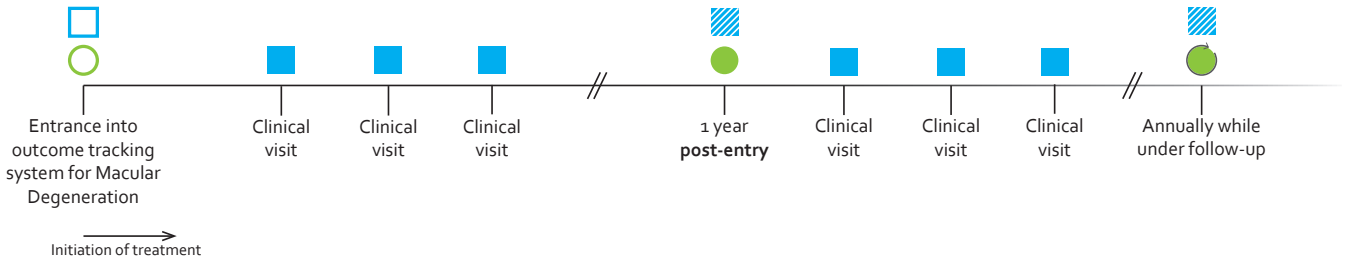
Outcomes

Patient Population	Measure	Supporting Information	Timing	Data Source
Disutility of Care				
All patients	Burden of treatment	Documentation of individual treatments received for macular degeneration in the current clinical visit	Each clinical visit	Clinical or administrative data
Neovascular macular disease patients	Complications of treatment	Endophthalmitis: severe intra-ocular inflammation within 3 months of last intra-ocular treatment, due to infectious or non-infectious causes		Clinical
Disease Control				
Neovascular macular disease patients	Presence of fluid, edema, or hemorrhage	Presence of intraretinal or subretinal fluid or haemorrhage that is attributable to activity of the neovascular lesion as determined by the treating ophthalmologist. This could be based on clinical examination or imaging	Each clinical visit	Clinical
Visual Functioning and Health Related Quality of Life				
All patients	Best corrected distance visual acuity – absolute & change	Distance visual acuity (best of uncorrected, corrected or pinhole) in the affected eye. Change in distance visual acuity should be calculated from baseline and previous visual acuity assessments	Each clinical visit	Clinical
	Reading and accessing information	Tracked via Brief Impact of Vision Impairment Profile (B_IVI)	Baseline; 1 year post initiation of treatment and tracked ongoing annually while under follow-up	Patient-reported
	Mobility and independence			
	Emotional well being			

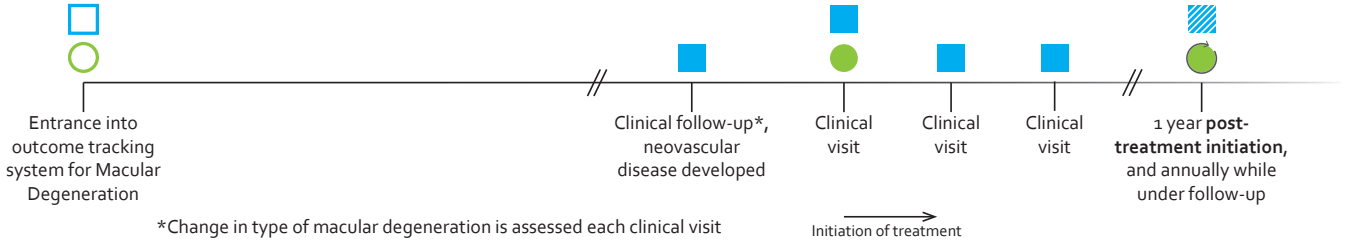
Follow-Up Timeline and Sample Questionnaires

The following timeline illustrates when Standard Set variables should be collected from patients, clinicians, and administrative sources. Links to the sample questionnaires may be found in the legend below.

Example 1: Patient with neovascular disease, receives treatment post diagnosis



Example 2: Patient with dry AMD, does not receive treatment and develops neovascular disease after certain period of time



The following questionnaires should be administered at the indicated time points

- Baseline Patient-Reported Form (link)
- Baseline Clinical Form (link)
- Each Clinical Visit Clinical Form (link)
- 1 Year Post Initiation of Treatment Patient-Reported Form (link)
- Annual (While Under Follow-Up) Patient-Reported Form (link)
- Annual (From Baseline) Clinical Form (link)

Collecting Patient-Reported Outcome Measures

Survey(s) Used	Licensing Information	Scoring Guide
Brief Impact of Vision Impairment Questionnaire (Brief IVI)	The Brief IVI includes costs for commercial use, and requires an agreement license. Contact Prof. Ecosse Lamoureux at ecosse@unimelb.edu.au for more information.	To facilitate the scoring of the Brief IVI, scoring instructions are provided in the Appendix on page 9.

The Growing ICHOM Community

By implementing the ICHOM Standard Sets, you become part of an expanding, international community of innovative health care providers dedicated to improving value for patients. To learn more about how ICHOM can assist your organization in implementing outcome measurement, contact us at implement@ichom.org, or visit http://www.ichom.org/measure.

Appendix

Scoring Instructions for the Brief Impact of Vision Impairment Questionnaire (B_IVI)

The IVI and B_IVI questionnaires

The Impact of Vision Impairment (IVI) questionnaire was developed to measure the effect of vision impairment on restriction of participation in daily activities. Initially, the IVI contained 32 items [1] but an updated, Rasch-scaled version of the IVI was published in 2006 with 28 items [2]. The 28 item version of the IVI is recommended for use. The Brief IVI (B_IVI) is a shortened version of the 28-item IVI questionnaire. It contains 15 items and has similar psychometric properties as the orignial.[3]

Assessment recommendations

The B_IVI can be interviewer or self administered. When interviewer administered, all text should be read out (including the preceding statements and the response options) and nothing should be altered or summarized. Preceding statements should be read out prior to every question (for example: "In the past month, how much has your eyesight interfered with…").

Domains

The B_IVI questionnaire comprises two domains:

1. Visual functioning (Q1-Q9)
2. Emotional well-being (Q10-Q15)

Response reporting format

The three response formats of the B_IVI questionnaire are:

REPORTING 1 (Q1-Q4)
3 = Not at all
2 = A little
1 = A fair amount
0 = A lot
8 = Don't do this for other reasons (excluded from analysis)

REPORTING 2 (Q5)
2 = Not at all
1 = A fair amount
0 = A lot
8 = Don't do this for other reasons (excluded from analysis)

REPORTING 3 (Q6-15)
3 = Not at all
2 = A little of the time
1 = A fair amount of the time
0 = A lot of the time

Calculating raw domain scores

Take the following steps to calculate overall and domain-specific raw scores for the B_IVI:

1. All items with a score of 8 ("Don't do this for other reasons") are excluded from analysis.
2. For a measure of overall vision-specific quality of life, calculate the average score of all the items.
3. To get domain scores, group the scores and calculate their average per domain, which gives two B_IVI raw scores:

1. **Visual functioning**
   Average of (Q1-Q9)
2. **Emotional well-being**
   Average of (Q10-Q15)

Rasch analysis

Rasch analysis of the raw B_IVI responses is necessary in order to:

a) assess the psychometric properties of the B_IVI and its two domains in your specific sample population, such as scale precision, unidimensionality, item fit, targeting, and differential item functioning, to ensure the B_IVI fits the Rasch model;

b) convert ordinal scores into those approximating interval-level measurement. Only interval measures should be used in parametric testing. Rasch analysis also improves measurement precision and increases sensitivity when assessing changes over time.

The authors of the B_IVI conduct Rasch analysis with Winsteps software (version 3.91.2, Chicago, Illinois, USA) using the the Andrich rating scale model, and can conduct Rasch analysis on the B_IVI data as a consultancy (for a fee) or as part of a collaboration (e.g. papers or grants). See below under "IVI contact info".

Translations

The IVI was originally developed in English. Every new language version of the IVI needs to be validated. Translations are avaiable for the 28-item version of the IVI in German, Malenesian, Chinese, Telugu and Hindi [5-8]. The IVI has also been validated in a population-based sample[8]. Because the B_IVI comprises subset of the IVI's 28 items, it is possible to use the German, Malenesian, Chinese, Telugu and Hindi versions of the IVI by simply removing the 13 irrelevant items and using only the 15 remaining items.

If you wish to translate the B_IVI into any other languages, please follow the following procedure.

Translation process

- The B_IVI should be translated and back translated by translators fluent in both languages
- Cognitive interviews with patients with vision impairment should be conducted to ensure the translated version is culturally and linguistically relevant
- The validation should be done in 100 - 200 patients*
- Please alert Prof Lamoureux if you would like to translate and validate the IVI in another language.
- Prof Lamoureux can provide advice on the translation/validation process if needed.

*Patients with any eye diseases and visual acuities (including healthy controls) may be included, although it is recommended that patients across the spectrum of vision impairment are represented to ensure there is enough variation in your sample.

IVI contact information

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References

Original version of IVI - 32 items

[1] Weih LM, Hassell JB, Keeffe JE. Assessment of the impact of vision impairment. Invest Ophthalmol Vis Sci. 2002 Apr;43(4):927-35.

Rasch analysis of IVI - 28 items

[2] Lamoureux EL, Pallant JF, Pesudovs K, Hassell JB, Keeffe JE. The Impact of Vision Impairment Questionnaire: an evaluation of its measurement properties using Rasch analysis. Invest Ophthalmol Vis Sci. 2006 Nov; 47(11):4732-41.

Rasch analysis of domain structure of the IVI

[3] Lamoureux EL, Pallant JF, Pesudovs K, Rees G, Hassell JB, Keeffe JE. The impact of vision impairment questionnaire: an assessment of its domain structure using confirmatory factor analysis and rasch analysis. Invest Ophthalmol Vis Sci. 2007 Mar; 48(3):1001-6.

Validation of the Brief IVI

[4] Fenwick EK, Man RE, Rees G, Keeffe J, Wong TY, Lamoureux EL. Reducing respondant burden: validation of the Brief Impact of Vision Impairment questionnaire. Qual Life Res. 2016. Epub ahead of print.

German

[5] Finger RP, Fenwick E, Marella M, Dirani M, Holz FG, Chiang PP, Lamoureux EL. The impact of vision impairment on vision-specific quality of life in Germany. Invest Ophthalmol Vis Sci. 2011 Jun 1;52(6):3613-9.

Melanesian

[6] O'Connor PM1, Scarr BC, Lamoureux EL, Le Mesurier RT, Keeffe JE. Validation of a quality of life questionnaire in the Pacific Island. Ophthalmic Epidemiol. 2010 Dec;17(6):378-86.

Telugu and Hindi

[7] Gothwal VK1, Reddy SP, Fathima A, Bharani S, Sumalini R, Bagga DK, Sudharman PM. Assessment of the impact of keratoconus on vision-related quality of life. Invest Ophthalmol Vis Sci. 2013 Apr 23;54(4):2902-10.

Mandarin Chinese

[8] Fenwick EK, Ong PG, Sabanayagam C, Rees G, Xie J, Holloway E, Cheng CY, Wong TY, Lim B, Tan PC, Lamoureux EL. Assessment of the psychometric properties of the Impact of Vision Impairment questionnaire in a population-based study: findings from the Singapore Chinese Eye Study. Qual Life Res. 2016. 25(4):871-80

Conversion Table for Snellen and LogMAR Acuity

The recommended reporting format for visual acuity is in LogMAR. To facilitate conversion from Snellen into LogMAR acuity scores, please refer to the following table.

Snellen Acuity (6 meters)	Snellen Acuity (20 feet)	LogMar Equivalent Acuity
6/3	20/10	-0.30
6/3.75	20/12.5	-0.20
6/4.8	20/16	-0.10
6/6	20/20	0.00
6/7.5	20/25	+0.10
6/9	20/30	+0.18
6/12	20/40	+0.30
6/15	20/50	+0.40
6/18	20/60	+0.48
6/24	20/80	+0.60
6/30	20/100	+0.70
6/36	20/120	+0.78
6/48	20/160	+0.90
6/60	20/200	+1.00
6/75	20/250	+1.10
6/96	20/320	+1.20
3/60 or 6/120	20/400	+1.30
1/60	20/1200	+1.78
Count fingers at 2 feet	Count fingers at 2 feet	+2.00
Hand motion at 2 feet	Hand motion at 2 feet	+3.00

References

[1] Holladay JT. Proper method for calculating average visual acuity. J Refract Surg. 1997 Jul-Aug;13(4):388-91.

[2] Kumar V, Banerjee S, Loo AV, Callear AB, Benson MT. Macular hole surgery with silicone oil. Eye (Lond). 2002 Mar;16(2):121-5.

Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM Macular Degeneration Standard Set as consistently as possible to the Working Group recommendation. ICHOM is actively preparing for benchmarking efforts based on this data, and all data submitted for comparisons will need to be transformed into the following data structure if not already structured as such. **We are happy to provide an Excel version of this data dictionary for technical use.**

Please timestamp all variables. Some Standard Set variables are collected at multiple timepoints, and we will ask you to submit these variables in a concatenated VARIABLEID_TIMESTAMP form for future analyses. For example, VARIABLEID_BASE (baseline); VARIABLEID_6MO (6 month follow-up); VARIABLEID_1YR (1 year follow-up), etc.

Case-Mix Variables

Variable ID:	N/A
Variable:	Patient ID
Definition:	Indicate the patient's medical record number
Supporting Definition:	This number will not be shared with ICHOM. In the case patient-level data is submitted to ICHOM for benchmarking or research purposes, a separate ICHOM Patient Identifier will be created and cross-linking between the ICHOM Patient Identifier and the medical record number will only be known at the treating institution
Inclusion Criteria:	All patients
Timing:	On all forms
Data Source:	Administrative or clinical
Type:	Numerical
Response Options:	According to institution

Demographic Factors

Variable ID:	AGE
Variable:	Age
Definition:	What is your date of birth?
Supporting Definition:	Age in years, calculated from birth date at commencement of therapy
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical or administrative data
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	SEX
Variable:	Sex
Definition:	Please indicate your sex at birth
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical or administrative data
Type:	Single answer
Response Options:	0 = Male 1 = Female 999 = Undisclosed

Variable ID:	ETNIC
Variable:	Ethnicity
Definition:	What is your ethnicity?
Supporting Definition:	Note that regulations on reporting ethnicity may differ per country
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Asian 2 = Black 3 = Hispanic 4 = White 5 = Mixed/multiple ethnic origins 888 = Other
Variable ID:	SMOKE
Variable:	Smoking status
Definition:	Do you smoke?
Supporting Definition:	Smoking status (of cigarettes, cigars or tobacco)
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Current smoker 2 = Former smoker 3 = Never smoked 999 = Unknown/Undisclosed

Baseline Functional Status

Variable ID:	DVA
Variable:	Distance visual acuity
Definition:	Indicate the patient's distance visual acuity
Supporting Definition:	Distance visual acuity (best of uncorrected, corrected using glasses or contact lenses, or pinhole) in the affected eye
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Numerical value
Response Options:	Numerical value preferably reported in LogMAR. Snellen may be used but needs to be converted to LogMAR. Please refer to page 13 for a Snellen to LogMAR conversion table.
Variable ID:	DVAFLWEYE
Variable:	Distance visual acuity in the fellow eye
Definition:	Indicate the patient's distance visual acuity in the other (non study) eye
Supporting Definition:	Distance visual acuity (best of uncorrected, corrected using glasses or contact lenses, or pinhole) in the fellow eye
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Numerical value
Response Options:	Numerical value preferably reported in LogMAR. Snellen may be used but needs to be converted to LogMAR. Please refer to page 13 for a Snellen to LogMAR conversion table.
Variable ID:	DVACHART
Variable:	Chart type
Definition:	Chart type used for distance visual acuity measurement
Supporting Definition:	Results preferably reported in LogMAR. Snellen may be used but needs to be converted to LogMAR.

Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Numerical value
Response Options:	1 = LogMAR 2 = Snellen
Variable ID:	DVADIST
Variable:	Distance at which distance visual acuity is measured
Definition:	Distance at which distance visual acuity is measured
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Numerical value
Response Options:	Record details of the distance at which visual acuity is measured

Baseline Clinical Status

Variable ID:	TYPEMDG
Variable:	Type of macular degeneration
Definition:	Indicate the type of macular degeneration
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline Each clinical visit to check for change
Data Source:	Clinical
Type:	Single answer
Response Options:	1 = Neovascular age related macular degeneration 2 = Myopic neovascular macular degeneration 3 = Other neovascular macular degeneration 4 = Polypoidal choroidal vasculopathy 5 = Dry/non-neovascular age related macular degeneration
Variable ID:	GEOATR
Variable:	Geographic atrophy
Definition:	Indicate the presence of geographic atrophy anywhere in the macular area that is not contiguous with the main lesion
Supporting Definition:	Geographic atrophy is defined as an area of hypopigmentation or hyperfluorescence of at least 250 µm in its minimum linear dimension with 2 of the 3 following characteristics: (i) circular shape, (ii) sharp borders, or (iii) visibility of choroidal vessels within the area of geographic atrophy
Inclusion Criteria:	All patients
Timing:	Baseline Each clinical visit to check for change
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = Not present 1 = Subfoveal (present and involving the subfoveal area) 2 = Extra-foveal (present, but not involving the subfoveal area)
Variable ID:	SUBFIB
Variable:	Subretinal fibrosis
Definition:	Indicate the presence of subretinal fibrosis
Supporting Definition:	Abnormal thickening of the subretinal tissue complex (material between Bruch's membrane and outer retina) anywhere in the macular area
Inclusion Criteria:	All patients
Timing:	Baseline Each clinical visit to check for change
Data Source:	Clinical
Type:	Single answer

Response Options:	0 = Not present 1 = Subfoveal (present and involving the subfoveal area) 2 = Extra-foveal (present, but not involving the subfoveal area)
Variable ID:	PED
Variable:	Pigment epithelial detachment
Definition:	Indicate the presence of pigment epithelial detachment
Supporting Definition:	Discrete elevations of the retinal pigment epithelium (RPE) anywhere in the macular area with solid (fibrovascular or haemorrhagic PED) or fluid (serous PED) matter below the corresponding retinal pigment epithelium
Inclusion Criteria:	All patients
Timing:	Baseline Each clinical visit to check for change
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = Not present 1 = Subfoveal (present and involving the subfoveal area) 2 = Extra-foveal (present, but not involving the subfoveal area)
Variable ID:	PEDTYPE
Variable:	Pigment epithelial detachment type
Definition:	Indicate the type of pigment epithelial detachment
Supporting Definition:	Solid (fibrovascular or haemorrhagic) or fluid (Serous) PED below the corresponding retinal pigment epithelium
Inclusion Criteria:	All patients If answered '1' or '2' on Pigment epithelial detachment (PED)
Timing:	Baseline Each clinical visit to check for change
Data Source:	Clinical
Type:	Single answer
Response Options:	1 = Solid (Fibrovascular or haemorrhagic) PED below the corresponding retinal pigment epithelium 2 = Fluid (Serous) PED below the corresponding retinal pigment epithelium

Associated Clinical History

Variable ID:	OCCOMORB
Variable:	Ocular comorbidities
Definition:	Indicate ocular comorbidities
Supporting Definition:	Select all that apply
Inclusion Criteria:	All patients
Timing:	Baseline Annually from baseline
Data Source:	Clinical
Type:	Multiple answers Separate multiple entries with ";"
Response Options:	1 = Retinal vascular disease (presence of any retinal vascular disease such as diabetic retinopathy, retinal vein occlusion, retinal artery occlusion) 2 = Other macular pathology (presence of any other macular pathology such as , diabetic macular edema, epiretinal membrane, macular hole, macular dystrophy etc.) 3 = Glaucoma or other optic neuropathy (confirmed diagnosis of glaucoma or other optic neuropathy has been made) 4 = Amblyopia (presence of amblyopia) 5 = Media opacity (presence of media opacity from cataract or corneal pathology etc.) 888 = Other
Variable ID:	PREVTREATMDG
Variable:	Previous macular degeneration treatment
Definition:	Indicate previous macular degeneration treatment in affected eye (multiple

	options possible)
Supporting Definition:	Select all that apply
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Multiple answers Separate multiple entries with ";"
Response Options:	0 = None 1 = Previous intravitreal anti-VEGF treatment 2 = Intravitreal steroid 3 = Photodynamic therapy 4 = Thermal laser photocoagulation 5 = Retinal radiation therapy 6 = Transpupillary thermotherapy 7 = Retinal surgical treatment 888 = Other 999 = Unknown/Undisclosed

Other Ocular Treatments

Variable ID:	CATSURGTX
Variable:	Cataract surgery
Definition:	Indicate if the patient received cataract surgery in the affected/study eye
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Each clinical visit to check for change
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes
Variable ID:	CATSURGTXDATE
Variable:	Date of cataract surgery
Definition:	Indicate the date of the cataract surgery
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'yes' on cataract surgery (CATSURGTX)
Timing:	Each clinical visit to check for change
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	YAGLASERTX
Variable:	YAG laser capsulotomy
Definition:	Indicate if the patient received YAG laser capsulotomy in the affected/study eye
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Each clinical visit to check for change
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes
Variable ID:	YAGLASERTXDATE
Variable:	Date of YAG laser capsulotomy
Definition:	Indicate the date of the YAG laser capsulotomy
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'yes' on YAG laser capsulotomy (YAGLASERTX)
Timing:	Each clinical visit to check for change
Data Source:	Clinical

Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	RETLASERTX
Variable:	Retinal laser
Definition:	Indicate if the patient received retinal laser therapy in the affected/study eye
Supporting Definition:	i.e. for macular edema or diabetic retinopathy
Inclusion Criteria:	All patients
Timing:	Each clinical visit to check for change
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes
Variable ID:	RETLASERTXDATE
Variable:	Date of retinal laser
Definition:	Indicate the date of the retinal laser therapy
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'yes' on retinal laser (RETLASERTX)
Timing:	Each clinical visit to check for change
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	VITRTX
Variable:	Vitrectomy
Definition:	Indicate if the patient received vitrectomy in the affected/study eye
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Each clinical visit to check for change
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes
Variable ID:	VITRTXDATE
Variable:	Date of vitrectomy
Definition:	Indicate the date of the vitrectomy
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'yes' on vitrectomy (VITRTX)
Timing:	Each clinical visit to check for change
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	CORNSURGTX
Variable:	Corneal surgery
Definition:	Indicate if the patient received corneal surgery in the affected/study eye
Supporting Definition:	i.e. graft, pterygium
Inclusion Criteria:	All patients
Timing:	Each clinical visit to check for change
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes
Variable ID:	CORNSURGTXDATE
Variable:	Date of corneal surgery
Definition:	Indicate the date of the corneal surgery
Supporting Definition:	N/A
Inclusion Criteria:	All patients

	If answered 'yes' on corneal surgery (CORNSURGTX)
Timing:	Each clinical visit to check for change
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY

Treatment Variables

Variable ID:	TREATRECEIV_NAME
Variable:	Name of treatments received
Definition:	Indicate the name of the received treatment for macular degeneration
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Each clinical visit
Data Source:	Clinical or administrative data
Type:	Multiple answers Separate multiple entries with ";"
Response Options:	0 = None 1 = Ranibizumab (Lucentis) 2 = Bevacizumab (Avastin) 3 = Pegaptanib (Macugen) 4 = Aflibercept (VEGF-trap/Eylea) 5 = Intravitreal steroid 6 = Photodynamic therapy 7 = Thermal laser photocoagulation 8 = Retinal radiation therapy 9 = Transpupillary thermotherapy 10 = Retinal surgical treatment 888 = Other 999 = Unknown/Undisclosed

Burden of Treatment

Burden of treatment is captured by TREATRECEIV_NAME. Please refer to "Treatment Variables" above.

Complications of Treatment

Variable ID:	ENDOPH
Variable:	Endophthalmitis
Definition:	Indicate if patient was diagnosed with endophthalmitis in the treated eye
Supporting Definition:	Severe intra-ocular inflammation within 3 months of last intra-ocular treatment, due to infectious or non-infectious causes
Inclusion Criteria:	Neovascular macular disease patients receiving treatment
Timing:	Each clinical visit
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Infectious endophthalmitis – suspected or proven intra-ocular infection. This includes all cases of suspected infectious endophthalmitis, whether culture-proven (i.e. positive culture) or those with a negative culture that behave clinically like infection (i.e. responsive to antibiotic treatment) 2 = Non-infectious endophthalmitis – not suspected to be caused by intra-ocular infection. This excludes all cases of suspected infectious endophthalmitis, whether culture-proven (i.e. positive culture) or those with a negative culture that behave clinically like infection (i.e. responsive to antibiotic treatment)

Disease Activity

Variable ID:	FLUID
Variable:	Presence of fluid, edema, or hemorrhage
Definition:	Indicate the presence of fluid, edema, or hemorrhage
Supporting Definition:	Presence of intraretinal or subretinal fluid or hemorrhage that is attributable to activity of the neovascular lesion as determined by the treating ophthalmologist. This could be based on clinical examination or imaging
Inclusion Criteria:	Neovascular macular disease patients receiving treatment
Timing:	Each clinical visit
Data Source:	Clinical
Type:	Single answer
Response Options:	1 = Active - presence of intraretinal or subretinal fluid or hemorrhage attributable to activity of the neovascular lesion 2 = Inactive - no signs of clinically significant activity

Visual Functioning and Health Related Quality of Life

Variable ID:	DVAAC
Variable:	Distance visual acuity – absolute & change
Definition:	Indicate the patient's distance visual acuity
Supporting Definition:	Distance visual acuity (best of uncorrected, corrected using glasses or contact lenses, or pinhole) in the affected eye
Inclusion Criteria:	All patients
Timing:	Each clinical visit
Data Source:	Clinical
Type:	Numerical value
Response Options:	Numerical value preferably reported in LogMAR. Snellen may be used but needs to be converted to LogMAR. Please refer to page 13 for a Snellen to LogMAR conversion table. Change in distance visual acuity should be calculated from baseline and previous visual acuity assessments.
Variable ID:	DVACHART

Variable:	Chart type
Definition:	Chart type used for distance visual acuity measurement
Supporting Definition:	Results preferably reported in LogMAR. Snellen may be used but needs to be converted to LogMAR.
Inclusion Criteria:	All patients
Timing:	Each clinical visit
Data Source:	Clinical
Type:	Numerical value
Response Options:	1 = LogMAR 2 = Snellen
Variable ID:	DVADIST
Variable:	Distance at which distance visual acuity is measured
Definition:	Distance at which distance visual acuity is measured
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Each clinical visit
Data Source:	Clinical
Type:	Numerical value
Response Options:	Record details of the distance at which visual acuity is measured
Variable ID:	B_IVI_Q01
Variable:	Question 1 of Brief IVI - Reading and accessing information
Definition:	In the past month, how much has your eyesight interfered with recognizing or meeting people?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = A fair amount 3 = A lot 8 = Don't do this for other reasons
Variable ID:	B_IVI_Q02
Variable:	Question 2 of Brief IVI - Reading and accessing information
Definition:	In the past month, how much has your eyesight interfered with reading labels or instructions on medicines?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = A fair amount 3 = A lot 8 = Don't do this for other reasons
Variable ID:	B_IVI_Q03
Variable:	Question 3 of Brief IVI - Reading and accessing information
Definition:	In the past month, how much has your eyesight interfered with operating household appliances and the telephone?
Supporting Definition:	N/A
Inclusion Criteria:	All patients

Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = A fair amount 3 = A lot 8 = Don't do this for other reasons
Variable ID:	B_IVI_Q04
Variable:	Question 4 of Brief IVI - Mobility and independence
Definition:	11: In the past month, how often has your eyesight made you go carefully to avoid falling or tripping?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little 2 = A fair amount 3 = A lot 8 = Don't do this for other reasons
Variable ID:	B_IVI_Q05
Variable:	Question 5 of Brief IVI - Reading and accessing information
Definition:	In the past month, how much has your eyesight interfered with reading ordinary size print? (for example newspapers)
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A fair amount 2 = A lot 8 = Don't do this for other reasons
Variable ID:	B_IVI_Q06
Variable:	Question 6 of Brief IVI - Mobility and independence
Definition:	In the past month, how often has your eyesight made you concerned or worried about your general safety at home?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little of the time 2 = A fair amount of the time 3 = A lot of the time
Variable ID:	B_IVI_Q07

Variable:	Question 7 of Brief IVI - Mobility and independence
Definition:	In the past month, how often has your eyesight made you concerned or worried about spilling or breaking things?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little of the time 2 = A fair amount of the time 3 = A lot of the time
Variable ID:	B_IVI_Q08
Variable:	Question 8 of Brief IVI - Mobility and independence
Definition:	In the past month, how often has your eyesight made you concerned or worried about your general safety when out of your home?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little of the time 2 = A fair amount of the time 3 = A lot of the time
Variable ID:	B_IVI_Q09
Variable:	Question 9 of Brief IVI - Mobility and independence
Definition:	In the past month, how often have you needed help from other people because of your eyesight?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little of the time 2 = A fair amount of the time 3 = A lot of the time
Variable ID:	B_IVI_Q10
Variable:	Question 10 of Brief IVI - Emotional well being
Definition:	In the past month, have you felt frustrated or annoyed because of your eyesight?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little of the time 2 = A fair amount of the time

	3 = A lot of the time
Variable ID:	B_IVI_Q11
Variable:	Question 11 of Brief IVI - Emotional well being
Definition:	In the past month, have you felt lonely or isolated because of your eyesight?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little of the time 2 = A fair amount of the time 3 = A lot of the time
Variable ID:	B_IVI_Q12
Variable:	Question 12 of Brief IVI - Emotional well being
Definition:	In the past month, how often have you worried about your eyesight getting worse?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little of the time 2 = A fair amount of the time 3 = A lot of the time
Variable ID:	B_IVI_Q13
Variable:	Question 13 of Brief IVI - Emotional well being
Definition:	In the past month, how often has your eyesight made you concerned or worried about coping with everyday life?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little of the time 2 = A fair amount of the time 3 = A lot of the time
Variable ID:	B_IVI_Q14
Variable:	Question 14 of Brief IVI - Emotional well being
Definition:	In the past month, have you felt like a nuisance or a burden because of your eyesight?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little of the time

	2 = A fair amount of the time 3 = A lot of the time
Variable ID:	B_IVI_Q15
Variable:	Question 15 of Brief IVI - Emotional well being
Definition:	In the past month, how much has your eyesight interfered with your life in general?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline 1 year post initiation of treatment and tracked ongoing annually while under follow-up
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = A little of the time 2 = A fair amount of the time 3 = A lot of the time

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Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change
2.0.1	Supporting Organizations	Included logo for new sponsor
2.0.2	The Growing ICHOM Community	Removed map and updated information
3.0.0	Data Dictionary	Adoption of B_IVI form, item responses modified to reflect new recommendation, inclusion of new scoring guide for B_IVI
3.0.1	Contact Information	Remove inactive email address: ichomteam@ichom.org

www.ichom.org