Diabetic Retinal Disease Staging System Update Effort, a project of the Mary Tyler Moore Vision Initiative. Le versant imagerie.

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Editorial

Updating the Staging System for Diabetic Retinal Disease

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Table 1. Limitations of the ETDRS and International DR Severity Scales and Goals for the Development of an Updated DRD Staging System

Limitations of the ETDRS and International DR Severity Scales	Goals for the Development of an Updated DRD Staging System
Do not evaluate the neural retina	Include evaluation of neural retinal pathology in DRD to elucidate early degenerative changes that may accompany or precede vascular lesions and to determine how neural abnormalities are correlated with visual function loss
Do not visualize the peripheral retina	Understand if peripheral retina is important for predicting future outcomes in eyes with DRD, because this may change whether we should routinely evaluate peripheral nonperfusion and lesions to best stage risk of DRD worsening for research and clinical efforts
Do not include molecular, pathophysiologic, or neurodegenerative changes that occur before the development of clinically evident retinopathy	Explore early changes in DRD that may lead to better characterization of preclinical abnormalities and therapeutic target development
Do not incorporate measures of systemic health	Include systemic health context (e.g., measures of glycemic control, blood pressure, and blood lipids) in the DRD staging system because these influence future anatomic and visual outcomes in persons with diabetes
Not well suited to document worsening or improvement of retinal neovascularization in eyes with PDR	Revise the PDR scale to describe key levels for both worsening and improvement of PDR. This will enable better characterization of eyes with PDR in natural history and under treatment for research and clinical purposes.
Do not address regression of DR severity in the setting of treatment	Clarify how improvement of ETDRS DR severity level during treatment with diabetes control, anti-VEGF, or steroids affects outcomes to understand whether such therapies modify underlying disease
Do not adequately incorporate severity stages for DME that are currently being used to drive care and evaluation of eyes with DME	Include severity stages for DME that specify involvement of the macula because this information is now incorporated into commonly used treatment algorithms
Are not directly tied to visual outcomes other than those based on best-corrected central visual acuity	Understand how additional aspects of functional vision, such as visual fields, contrast sensitivity, metamorphopsia, and low luminance acuity, change in DRD. This may facilitate development of therapies addressing DRD severity levels that do not directly affect central visual acuity and provide additional registrable end points for regulatory approval.
Are not quantitative	Aim to develop a staging system and severity scales that can be used to quantitate DRD pathology for easier use in clinical research
Difficult to use in practice	Develop a revised staging system that is easy to use in practice

DME = diabetic macular edema; DR = diabetic retinopathy; DRD = diabetic retinal disease; PDR = proliferative diabetic retinopathy.

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Visual Function Measurements in Eyes With Diabetic Retinopathy: An Expert Opinion on Available Measures

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Clinical Relevance: Visual function impairment from diabetic retinopathy can have a considerable impact on patient's quality of life. Best-corrected visual acuity (BCVA) is most commonly used to assess visual function and guide clinical trials. However, BCVA is affected late in the disease process, is not affected in early disease, and does not capture some of the visual disturbances described by patients with diabetes. The goal of this report is to evaluate the relationship between diabetic retinal disease (DRD) and visual function parameters to determine which if any of them may be used in a future DRD staging system.

Methods: The visual functions working group was 1 of 6 areas of DRD studied as part of the DRD staging system update, a project of the Mary Tyler Moore Vision Initiative. The working group identified 12 variables of possible interest, 7 of which were judged to have sufficient preliminary data to suggest an association with DR to warrant further review: microperimetry, static automated perimetry, electroretinogram (ERG) oscillatory potentials, flicker ERG, low luminance visual acuity (LLVA), contrast sensitivity (CS), and BCVA. The objective field analyzer (OFA) was added after subsequent in-person workshops.

Results: Currently, the only visual function test available for immediate use is BCVA; the remaining tests are either promising (within 5 years) or have potential (>5 years) use. Besides BCVA, most visual function tests had a limited role in current clinical care; however, LLVA, CS, flicker ERG, and OFA demonstrated potential for screening and research purposes.

Conclusions: Although current visual function tests are promising, future prospective studies involving patients with early and more advanced retinopathy are necessary to determine if these tests can be used clinically or as endpoints for clinical studies.

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Imaging Modalities for Assessing the Vascular Component of Diabetic Retinal Disease: Review and Consensus for an Updated Staging System

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Purpose: To review the evidence for imaging modalities in assessing the vascular component of diabetic retinal disease (DRD), to inform updates to the DRD staging system.

Design: Standardized narrative review of the literature by an international expert workgroup, as part of the DRD Staging System Update Effort, a project of the Mary Tyler Moore Vision Initiative. Overall, there were 6 workgroups: Vascular Retina, Neural Retina, Systemic Health, Basic and Cellular Mechanisms, Visual Function, and Quality of Life.

Participants: The Vascular Retina workgroup, including 16 participants from 4 countries.

Methods: Literature review was conducted using standardized evidence grids for 5 modalities: standard color fundus photography (CFP), widefield color photography (WFCP), standard fluorescein angiography (FA), widefield FA (WFFA), and OCT angiography (OCTA). Summary levels of evidence were determined on a validated scale from I (highest) to V (lowest). Five virtual workshops were held for discussion and consensus.

Main Outcome Measures: Level of evidence for each modality.

Results: Levels of evidence for standard CFP, WFCP, standard FA, WFFA, and OCTA were I, II, I, I, and II respectively. Traditional vascular lesions on standard CFP should continue to be included in an updated staging system, but more studies are required before they can be used in posttreatment eyes. Widefield color photographs can be used for severity grading within the area covered by standard CFPs, although these gradings may not be directly interchangeable with each other. Evaluation of the peripheral retina on WFCP can be considered, but the method of grading needs to be clarified and validated. Standard FA and WFFA provide independent prognostic value, but the need for dye administration should be considered. OCT angiography has significant potential for inclusion in the DRD staging system, but various barriers need to be addressed first.

Conclusions: This study provides evidence-based recommendations on the utility of various imaging modalities for assessment of the vascular component of DRD, which can inform future updates to the DRD staging system. Although new imaging modalities offer a wealth of information, there are still major gaps and unmet research needs that need to be addressed before this potential can be realized.

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A New Approach to Staging Diabetic Eye Disease

Staging of Diabetic Retinal Neurodegeneration and Diabetic Macular Edema

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Topic: The goal of this review was to summarize the current level of evidence on biomarkers to quantify diabetic retinal neurodegeneration (DRN) and diabetic macular edema (DME).

Clinical relevance: With advances in retinal diagnostics, we have more data on patients with diabetes than ever before. However, the staging system for diabetic retinal disease is still based only on color fundus photographs and we do not have clear guidelines on how to incorporate data from the relatively newer modalities into clinical practice.

Methods: In this review, we use a Delphi process with experts to identify the most promising modalities to identify DRN and DME. These included microperimetry, full-field flash electroretinogram, spectral-domain OCT, adaptive optics, and OCT angiography. We then used a previously published method of determining the evidence level to complete detailed evidence grids for each modality.

Results: Our results showed that among the modalities evaluated, the level of evidence to quantify DRN and DME was highest for OCT (level 1) and lowest for adaptive optics (level 4).

Conclusion: For most of the modalities evaluated, prospective studies are needed to elucidate their role in the management and outcomes of diabetic retinal diseases.

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Rationale of Basic and Cellular Mechanisms Considered in Updating the Staging System for Diabetic Retinal Disease

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Purpose: Hyperglycemia is a major risk factor for early lesions of diabetic retinal disease (DRD). Updating the DRD staging system to incorporate relevant basic and cellular mechanisms pertinent to DRD is necessary to better address early disease, disease progression, the use of therapeutic interventions, and treatment effectiveness.

Design: We sought to review preclinical and clinical evidence on basic and cellular mechanisms potentially pertinent to DRD that might eventually be relevant to update the DRD staging system.

Participants: Not applicable.

Methods: The Basic and Cellular Mechanisms Working Group (BCM-WG) of the Mary Tyler Moore Vision Initiative carefully and extensively reviewed available preclinical and clinical evidence through multiple iterations and classified these.

Main Outcome Measures: Classification was made into evidence grids, level of supporting evidence, and anticipated future relevance to DRD.

Results: A total of 40 identified targets based on pathophysiology and other parameters for DRD were grouped into concepts or evaluated as specific candidates. VEGFA, peroxisome proliferator-activated receptor-alpha related pathways, plasma kallikrein, and angiopoietin 2 had strong agreement as promising for use as biomarkers in diagnostic, monitoring, predictive, prognostic, and pharmacodynamic responses as well as for susceptibility/risk biomarkers that could underlie new assessments and eventually be considered within an updated DRD staging system or treatment, based on the evidence and need for research that would fit within a 2-year timeline. The BCM-WG found there was strong reason also to pursue the following important concepts regarding scientific research of DRD acknowledging their regulation by hyperglycemia: inflammatory/cytokines, oxidative signaling, vasoprotection, neuroprotection, mitophagy, and nutrient/microbiome.

Conclusion: Promising targets that might eventually be considered within an updated DRD staging system or treatment were identified. Although the BCM-WG recognizes that at this stage little can be incorporated into a new DRD staging system, numerous potential targets and important concepts deserve continued support and research, as they may eventually serve as biomarkers and/or therapeutic targets with measurable benefits to patients with diabetes.

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Measuring Quality of Life in Diabetic Retinal Disease: A Narrative Review of Available Patient-Reported Outcome Measures

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Topic: Several patient-reported outcome measures (PROMs) are available to measure health-related quality of life (HRQoL) in patients with late-stage clinical diabetic retinal diseases (DRDs). However, an understanding of the psychometric properties of PROMs is needed to assess how they could relate to severity levels of a revised DRD grading system. This narrative review assessed the available generic-, vision-, and DRD-related PROMs used in DRD research and highlights areas for improvement.

Clinical Relevance: Diabetic retinal disease is a common complication of diabetes and can lead to sight-threatening complications with a devastating effect on HRQoL.

Methods: The Quality of Life working group is one of 6 working groups organized for the DRD Staging System Update Effort, a project of the Juvenile Diabetes Research Foundation Mary Tyler Moore Vision Initiative. PubMed, Cochrane Library, Embase, and Google Scholar databases were searched using core keywords to retrieve ophthalmology-related review articles, randomized clinical trials, and prospective, observational, and cross-sectional studies in the English language. A detailed review of 12 PROMs (4 QoL questionnaires and 8 utilities) that met a minimum level of evidence (LOE) was conducted. The relevance of each PROM to DRD disease stage and Biomarker Qualification guidelines (*Biomarkers, EndpointS, and other Tools*) categories was also defined.

Results: The National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25), Impact of vision impairment-computerized adaptive testing, and Diabetic Retinopathy and Macular Edema Computerized Adaptive Testing System had a LOE of II in detecting change due to late-stage DRD (diabetic macular edema), although several areas for improvement (e.g., psychometrics and generalizability) were identified. Other PROMs, particularly the utilities, had a LOE of III due to cross-sectional evidence in late-stage clinical DRD. Although the NEI VFQ-25 has been the most widely used PROM in late-stage DRD, more work is required to improve its multidimensional structure and other psychometric limitations. No PROM was deemed relevant for subclinical or early/mid-DRD.

Conclusion: This narrative review found that the most commonly used PROM is NEI VFQ-25, but none meets the ideal psychometric, responsiveness, and clinical setting digital administration requirements that could be included in an updated DRD staging system for diagnosis and monitoring of DRD progression.

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Role of Systemic Factors in Improving the Prognosis of Diabetic Retinal Disease and Predicting Response to Diabetic Retinopathy Treatment

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Topic: To review clinical evidence on systemic factors that might be relevant to update diabetic retinal disease (DRD) staging systems, including prediction of DRD onset, progression, and response to treatment.

Clinical relevance: Systemic factors may improve new staging systems for DRD to better assess risk of disease worsening and predict response to therapy.

Methods: The Systemic Health Working Group of the Mary Tyler Moore Vision Initiative reviewed systemic factors individually and in multivariate models for prediction of DRD onset or progression (i.e., prognosis) or response to treatments (prediction).

Results: There was consistent evidence for associations of longer diabetes duration, higher glycosylated hemoglobin (HbA1c), and male sex with DRD onset and progression. There is strong trial evidence for the effect of reducing HbA1c and reducing DRD progression. There is strong evidence that higher blood pressure (BP) is a risk factor for DRD incidence and for progression. Pregnancy has been consistently reported to be associated with worsening of DRD but recent studies reflecting modern care standards are lacking. In studies examining multivariate prognostic models of DRD onset, HbA1c and diabetes duration were consistently retained as significant predictors of DRD onset. There was evidence of associations of BP and sex with DRD onset. In multivariate prognostic models examining DRD progression, retinal measures were consistently found to be a significant predictor of DRD with little evidence of any useful marginal increment in prognostic information with the inclusion of systemic risk factor data apart from retinal image data in multivariate models. For predicting the impact of treatment, although there are small studies that quantify prognostic information based on imaging data alone or systemic factors alone, there are currently no large studies that quantify marginal prognostic information within a multivariate model, including both imaging and systemic factors.

Conclusion: With standard imaging techniques and ways of processing images rapidly evolving, an international network of centers is needed to routinely capture systemic health factors simultaneously to retinal images so that gains in prediction increment may be precisely quantified to determine the usefulness of various health factors in the prognosis of DRD and prediction of response to treatment.

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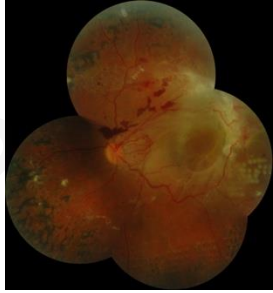
Photographie standard du fond d'œil (CFP)



- **Utilisation éprouvée** : La CFP standard reste un outil essentiel pour le dépistage et la stratification des risques dans la rétinopathie diabétique, notamment pour les lésions vasculaires comme les hémorragies et les microanévrismes.

- **Classification fiable** : Elle continue d'être incluse dans les systèmes de classification actuels tels que l'ETDRS.

- **Évidence clinique** : Basée sur des études prospectives bien établies, elle est classée au niveau de preuve I.

- **Limitations** : Les systèmes actuels ne prennent pas en compte les yeux traités avec des injections anti-VEGF, ce qui limite leur application clinique dans ces cas.

- **Perspective d'amélioration** : L'intégration de techniques d'intelligence artificielle pourrait permettre une évaluation plus quantitative des lésions rétiniennes.

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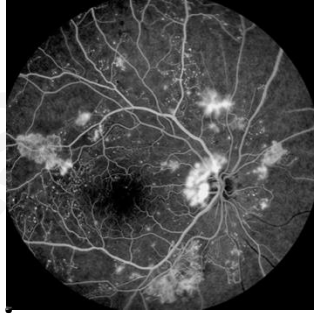
Photographie grand champ et ultra grand champ du fond d'œil (WFCP)

- **Couverture élargie** : Le WFCP permet d'évaluer des zones de la rétine périphérique qui ne sont pas visibles avec la CFP standard (minimum 110°)
- **Pronostic amélioré** : Les lésions périphériques identifiées par WFCP montrent que le stade de la RD est aggravé dans 8.3 à 19% des yeux et peuvent être associées à un risque accru de progression de la RD (X4 à 4 ans).
- **Niveau de preuve II** : Bien que les données actuelles montrent son utilité, des recherches supplémentaires sont nécessaires pour l'inclusion complète dans les systèmes de classification.
- **Adaptation recommandée** : Le WFCP peut être utilisé pour le dépistage (7 ETDRS), mais ses résultats ne sont pas directement interchangeables avec ceux de la CFP standard.
- **Perspectives futures** : Le développement d'approches automatisées pour analyser les images WFCP pourrait améliorer la précision diagnostique.

Silva PS, Cavallerano JD, Sun JK, et al. Peripheral lesions identified by mydriatic ultrawide field imaging: distribution and potential impact on diabetic retinopathy severity. Ophthalmology. 2013;120:2587e2595.
Aiello LP, Odia I, Glassman AR, et al. Comparison of early treatment diabetic retinopathy study standard 7-field imaging with ultrawide-field imaging for determining severity of diabetic retinopathy. JAMA Ophthalmol. 2019;137:65e73.
Domalpally A, Barrett N, Reimers J, Blodi B. Comparison of ultra-widefield imaging and standard imaging in assessment of early treatment diabetic retinopathy severity scale. Ophthalmol Sci. 2021;1:100029.
Price LD, Au S, Chong NV. Optomap ultrawide field imaging identifies additional retinal abnormalities in patients with diabetic retinopathy. Clin Ophthalmol. 2015;9:527e531.
Silva PS, El-Rami H, Barham R, et al. Hemorrhage and/or microaneurysm severity and count in ultrawide field images and early treatment diabetic retinopathy study photography. Ophthalmology. 2017;124:970e976.

Angiographie à la fluorescéine standard (FA)



- **Visualisation des vaisseaux** : La FA standard est utilisée pour évaluer les anomalies vasculaires telles que les zones de non-perfusion et les micro-anévrismes.

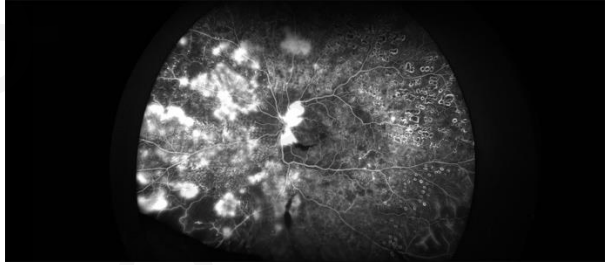
- **Pronostic indépendant** : Elle offre une valeur prédictive supplémentaire pour la progression de la RD par rapport à la CFP standard.

- **Niveau de preuve I** : Les études montrent une corrélation entre les caractéristiques de la FA et le risque de progression vers une RD proliférante (PDR).

- **Limite d'utilisation** : La nécessité d'une injection de colorant intraveineux limite son utilisation généralisée dans le dépistage de routine.

- **Utilisation ciblée** : Recommandée pour les stades modérés à sévères de la RD, où des informations supplémentaires sur la perfusion rétinienne sont nécessaires.

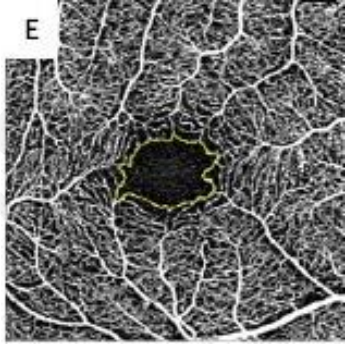
Angiographie à la fluorescéine en ultra grand champ (WFFA)



- **Extension de l'imagerie** : Comme la FA standard, mais avec une couverture plus large, permettant une évaluation plus complète des zones périphériques.
- **Prédiction des risques** : Les caractéristiques telles que les indices de fuite rétinienne sur WFFA sont associées à un besoin accru de traitements anti-VEGF et un risque d'aggravation de 1,7 fois plus importante à 4 ans.
- **Niveau de preuve I** : Soutenue par des études longitudinales démontrant son utilité dans la prédiction de la progression de la RD.
- **Problèmes de standardisation** : Des différences dans les résultats entre la WFFA et l'OCTA ont été observées, nécessitant des recherches supplémentaires.
- **Potentiel de l'IA** : L'analyse quantitative par IA pourrait améliorer l'utilité clinique de la WFFA dans l'évaluation de la RD.

Silva PS, Liu D, Glassman AR, et al. Assessment of fluorescein angiography nonperfusion in eyes with diabetic retinopathy using ultrawidefield retinal imaging. Retina. 2022;42:1302e1310.
Silva PS, Dela Cruz AJ, Ledesma MG, et al. Diabetic retinopathy severity and peripheral lesions are associated with nonperfusion on ultrawide field angiography. Ophthalmology. 2015;122:2465e2472.
Jiang AC, Sevgi DD, Mugnaini C, et al. Predictive assessment of quantitative ultra-widefield angiographic features for future need for anti-VEGF therapy in diabetic eye disease. J Pers Med. 2022;12:608.
Marcus DM, Silva PS, Liu D, et al. Association of predominantly peripheral lesions on ultra-widefield imaging and the risk of diabetic retinopathy worsening over time. JAMA Ophthalmol. 2022;140:946e954.
Silva PS, Marcus DM, Liu D, et al. Association of ultrawidefield fluorescein angiography-identified retinal nonperfusion and the risk of diabetic retinopathy worsening over time. JAMA Ophthalmol. 2022;140:936e945.

OCT- Angiographie



•**Non-invasif** : L'OCTA fournit une visualisation détaillée des microvaisseaux rétiniens sans besoin d'injections de colorant. Intérêt des analyses quantitatives+++

•**Profondeur d'analyse** : Capable de fournir des informations sur différents plexus capillaires rétiniens et la zone avasculaire fovéale.

•**Niveau de preuve II** : Bien que prometteuse, l'OCTA nécessite des études supplémentaires pour standardiser ses mesures et améliorer sa fiabilité.

•**Problèmes techniques** : Des variations entre les appareils commerciaux et des artefacts d'image limitent actuellement son adoption généralisée. Trop souvent utilisé en 3X3 alors que des zones plus larges offriraient plus d'informations.

•**Avenir prometteur** : Une validation plus poussée pourrait permettre à l'OCTA de devenir un outil de prédiction clé dans un système de classification mis à jour pour la RD

Sun Z, Yang D, Tang Z, et al. Optical coherence tomography angiography in diabetic retinopathy: an updated review. Eye (Lond). 2021;35:149e161.
Chua J, Sim R, Tan B, et al. Optical coherence tomography angiography in diabetes and diabetic retinopathy. J Clin Med. 2020;9:1723.

Table 1. Level of Evidence for Various Assessment Modalities of Retinal Vascular Component

Assessment Modality	Level of Evidence*			
	I	*II*	*III*	*IV–V*
Standard CFP	X			
WFCP		X		
Standard FA	X			
WFFA	X			
OCTA		X		

Table 2. Readiness for Adoption and Relevant Stages of DRD for Various Assessment Modalities of Retinal Vascular Component

	Ready (for Current Use or Within the Next 1–2 Years)	Promising (Unmet, but Defined Research Needs That Can Be Accomplished Within the Next 5 Years)	Potential (Unmet Research Needs That Will Need > 5 Years to Accomplish)
Subclinical DRD (no clinical DR)	Standard CFP* WFCP*	OCTA	
Early-stage clinical DRD (mild NPDR)	Standard CFP Standard FA WFFA	WFCP OCTA	
Mid-stage clinical DRD (moderate to severe NPDR)	Standard CFP Standard FA WFFA	WFCP OCTA	
Late-stage clinical DRD (PDR)	Standard CFP WFCP	OCTA†	

CFP = color fundus photographs; DR = diabetic retinopathy; DRD = diabetic retinal disease; FA = fluorescein angiography; NPDR = nonproliferative diabetic retinopathy; OCTA = OCT angiography; PDR = proliferative diabetic retinopathy; WFCP = widefield color photographs; WFFA = widefield fluorescein angiography.

*For screening of individuals with no clinical DR.

†For evaluation and differentiation of new vessels versus intraretinal microvascular abnormalities.

Quelles sont les recommandations?

- Meilleure évaluation des différents examens d'imagerie sous traitement (IVT et PPR)+++
- Développement des valeurs quantitatives sur CFP et WFCP par des études prospectives longitudinales ➔ intérêt de l'IA
- Standardisation et amélioration des mesures en OCT-A par des données prospectives et longitudinales, à partir de zones d'analyses plus larges (progression RD, OMD et AV)

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Table 3. BEST Biomarker Categories for Various Assessment Modalities of Retinal Vascular Component

Assessment Modality	BEST Category* (Based on Currently Available Evidence and Reasonable Anticipated Future Relevance)						
	Diagnostic	*Monitoring*	*Predictive*	*Prognostic*	*Pharmacodynamic/ Response*	*Safety*	*Susceptibility/Risk*
Standard CFP	X	X	Possible	X	Possible		
WFCP	X	X	Possible	X	Possible		
Standard FA	X	X	Possible	X	Possible		
WFFA	X	X	Possible	X	Possible		
OCTA	X	X	Possible	X	Possible		Possible

CFP = color fundus photographs; FA = fluorescein angiography; OCTA = OCT angiography; WFCP = widefield color photographs; WFFA = widefield fluorescein angiography.

*For definitions see FDA-NIH Biomarker Working Group. BEST (Biomarkers, EndpointS, and other Tools) Resource. Updated September 23, 2020. Accessible at https://www.ncbi.nlm.nih.gov/books/NBK326791/.