

## White Paper

# Ophthalmology Site Certification



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## 1. Introduction

Ophthalmology studies employ technical endpoints requiring specialized capabilities and a detailed understanding of ophthalmic research methods. Correct implementation of the study protocol and consistency of data across sites may be achieved by ensuring that sites and personnel are trained to a high standard and will deploy testing in a consistent manner. Site certification is an important tool used to standardize procedures and add credibility to clinical study data.

This paper provides a brief overview of points to consider in site certification for ophthalmology studies.

## 2. What is Site Certification?

Site certification ensures data quality, integrity and accuracy. In ophthalmology, the process identifies standardized approaches to ocular assessments to ensure that data are consistent within and between sites. Site certification provides assurance that sites adhere to the



highest professional standards of research conduct and utilize the same standards and methods when undertaking the same assessments. Certification involves checking that a site has the correct procedures in place, and that those procedures are consistently applied every time they are employed.

Certification is time-consuming, and relies on open communication between the study coordinator, site monitor and any third party certifying agency. It may take a technician numerous attempts to perfect a test such as fundus photography. Sites are usually required to have two certified technicians so ensuring that a site has sufficient personnel is critical.

The ideal ophthalmology study site will have conducted many ophthalmic studies in the past. Study coordinators will be experienced and certified for the tests that are included in the protocol. If a site is not certified, certification should be obtained from an independent third party. Whilst private practices or research sites may have many patients, these study sites may not always produce good data. Recruitment expectations should be balanced with data quality. For research naïve sites, sponsors should INSIST on certification for primary endpoints.

## 3. An Example of Certification for Ophthalmology Studies

For a wet age-related macular degeneration protocol, sponsors should consider sites that are certified in visual acuity (ETDRS), ocular coherence tomography (OCT) and fundus photography. Sites should use the same equipment and a central reading center, with the

same reader, should read OCT and fundus photography assessments for consistency. Standardization of visual acuity assessment is outlined in more detail overleaf.

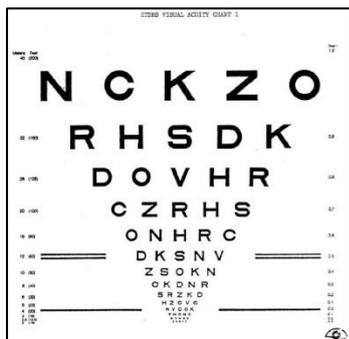
#### 4. Visual Acuity Certification

As the function of the eye is to see, and ophthalmic patients typically wish for their vision to improve, the most common primary endpoints in ophthalmology studies are related to visual function. Assessment is possible through a number of functional diagnostic tests that include visual acuity testing, which is used to assess how sharp images are. Standardization of visual acuity scores allow use of visual acuity as a continuous variable for statistical purposes. The most basic standardization is to check that distances for visual acuity testing lanes are correct and that lighting levels are correct and consistent. Certification relies on demonstrating that all aspects of visual acuity testing are standardized correctly and applied consistently to each examination. Study monitors should be trained in visual acuity lane measurement.



#### 5. ETDRS Certification

The ETDRS (Early Treatment Diabetic Retinopathy Study) protocol, designed to eliminate inaccuracies in the Snellan and Sloan acuity tests, has become the 'gold standard' in measurement of visual acuity. Correct evaluation of the ETDRS test should be conducted under standard lighting conditions, and scoring methods should be standardized. The site should have appropriate study lens frames and kits, and the coordinator should have sufficient lighting to record the test results in the dark examination room. ETDRS certification requires that both ophthalmic examination lanes and technicians are certified.



#### 6. Monitoring Contribution to Certification

Experienced clinical managers and monitors, with a background in optometry or ophthalmic study coordination, understand the methods used for assessments and therefore have the ability to interpret data, not just check them.

- Monitoring best practice dictates that monitors should be trained to validate visual examination lane measurement;
- Monitors should coordinate checklists of tests that require certification;

- Data managers should design ophthalmic study case report forms that are clear, unambiguous and facilitate eye examinations;
- Study personnel should share information and lessons learned from monitors.

## **7. Summary**

Site certification promotes standardization in ophthalmic studies by identifying standards for practice that ensure consistency in testing methods within and across study sites.

## **8. About CROMSOURCE**

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