

BCVA Certification



MERIT is an innovative clinical trial endpoint services expert providing reliable and attentive expertise in our therapeutic areas. We deliver reliable endpoint services in global clinical trials to our CRO, pharmaceutical, and biotech partners. Together our work advances and accelerates the improvement of therapeutic options for patients worldwide.

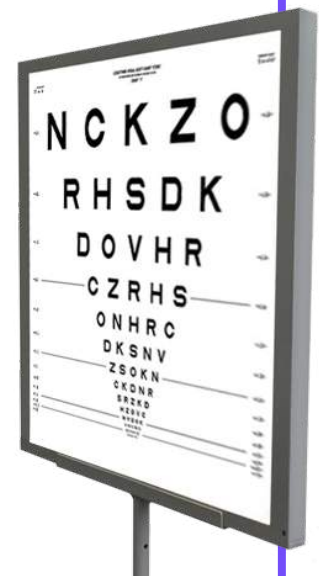
BCVA SERVICES

- ✓ Full, Abbreviated, and Express Certifications for VA Examiners
- ✓ Full and Express Certifications for VA Rooms
- ✓ Certificates Maintained in EXCELSIOR™
- ✓ Confirmation of Acceptable BCVA Equipment
- ✓ Scheduling, Tracking & Reporting of BCVA Certification Study Activities
- ✓ Visual Acuity Certifications: ETDRS, Low Luminance, Contrast Sensitivity & Reading Assessments
- ✓ VA Room Equipment Procurement



With MERIT, you benefit from the following:

- **EXPERT BCVA CERTIFICATION TEAM:** Our team has extensive clinical and teaching backgrounds in ophthalmology and/or optometry, and have performed BCVA certification in multiple ophthalmology clinical trials
- **CERTIFICATION TRACKING AND DATA REVIEW IN A SINGLE SYSTEM:** Efficient and accurate upload and tracking of study certifications in our proprietary software, EXCELSIOR. The same system can be used for centralized data review of BCVA source documents
- **FLEXIBLE VA EXAMINER CERTIFICATION MODEL:** MERIT offers full, abbreviated, and express certifications for VA examiners to support faster study startup times

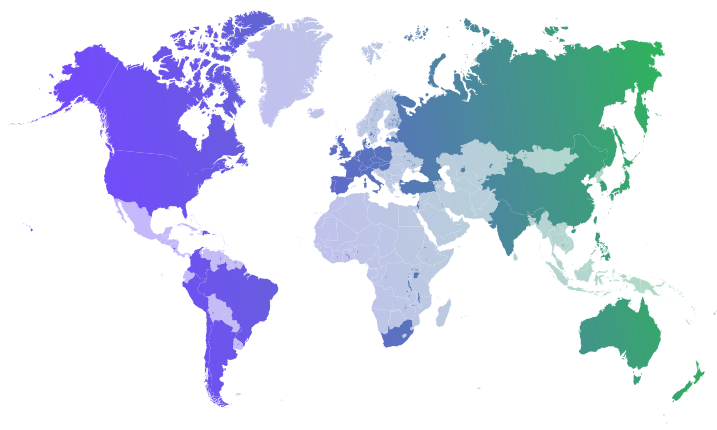


EXCELSIOR™

EXCELSIOR, our cloud-based software solution, is designed for ophthalmology studies and is FDA 510(K) cleared as well as HIPAA, 21 CFR Part 11, and GDPR compliant. EXCELSIOR enhances the efficiency and accuracy of your ophthalmology data collection and interpretation.

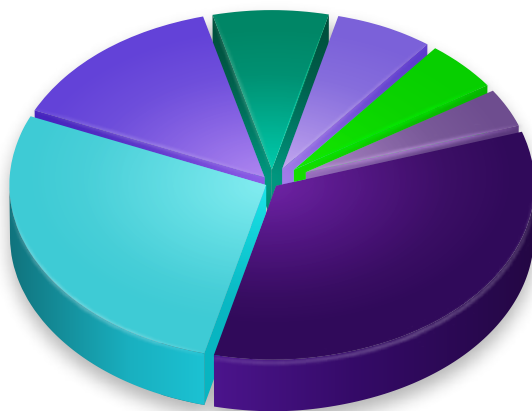


EXPERIENCE BY THE NUMBERS



| | |
|---------------------|--------|
| TOTAL TRIALS HOSTED | 315 |
| TOTAL SITES | 3,180 |
| COUNTRIES | 58 |
| TOTAL USERS | 20,604 |
| TOTAL PARTICIPANTS | 57,298 |

OPHTHALMOLOGY STUDIES BY INDICATION



- 74 AMD
Age-Related Macular Degeneration (AMD)
- 61 DR/DME
Diabetic Retinopathy/
Diabetic Macular Edema (DR/DME)
- 31 Inherited Retinal
Diseases
- 17 IOL/Corneal
Intraocular Lenses (IOL)/Corneal
- 15 Safety
- 11 RVO
- 9 Uveitis

IN-DEPTH INFORMATION ON MERIT'S BCVA SERVICES



Full, Abbreviated, and Express Certifications for VA Examiners

- Development of detailed BCVA and refraction procedural manuals for ophthalmic technicians for certification
- Full site examiner certification to include training session and certification assessment
- Express examiner certification assessed through questionnaire, online meeting, or phone call



Confirmation of Acceptable Equipment

- Review and confirmation of acceptability of BCVA equipment may be performed at sponsor's request



Full and Express Certifications for VA Rooms

- Evaluation of room condition including lane environment, space, and equipment access
- Checklist for lane preparation provided prior to certification
- Certification assessment and documentation



Upload and Centralized Data Review of BCVA Source Documents

- MERIT's cloud-based EXCELSIOR platform allows immediate upload of source documents directly from qualified sites to a central database for centralized data review, without installing software or configuring firewalls. This elevates efficiency and accuracy in the acquisition and pload of BCVA source docs
- Our centralized data review of BCVA source documents in EXCELSIOR can easily be configured to meet sponsor and study requirements. Our expert data review team can help ensure BCVA values are accurate



Certificates Maintained in EXCELSIOR™

- Examiner and room certification forms maintained in EXCELSIOR



Scheduling, Tracking & Reporting of BCVA Certification Study Activities

- Distribute BCVA and refraction procedural manual to site staff
- Develop and distribute a site survey to discover who at the site will need to certify for BCVA and refraction procedures as well as information about the site equipment
- Track and schedule site training and certification
- Provide coordination among sites, certification team, Sponsor, and others (as applicable)



VA Room Equipment Procurement

- Project Management staff coordinate with sites, equipment vendors, and the study team to order required VA equipment for sites, as needed



IMPORTANCE OF ETDRS BCVA



ETDRS BCVA

Early Treatment Diabetic Retinopathy Study (ETDRS) BCVA is the primary endpoint for vision in many ophthalmic clinical trials. Standardized measurement and collection of BCVA is key for successful trials. Standardization through certification and centralized data review supports accurate quantification of vision and consistent measures of vision change.



ETDRS BCVA Certification

BCVA certification assures Sponsors that clinical trial site personnel are adequately trained in performing BCVA assessments in a standardized and correct way. In addition, lane certification ensures that all lane and exam room requirements are met.



Centralized Data Review of ETDRS BCVA

Given the importance of BCVA as the primary endpoint for the majority of ophthalmic clinical trials, prompt and accurate review of the BCVA source documents by an ophthalmology specialist is critical. Centralized data review allows sponsors to provide more efficient oversight, with the potential for reduced risk and lower costs.



Connect with us to learn more about how our expertise and approach can support bringing your product to market on-time and on-budget. Your success is our priority.

START A CONVERSATION

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