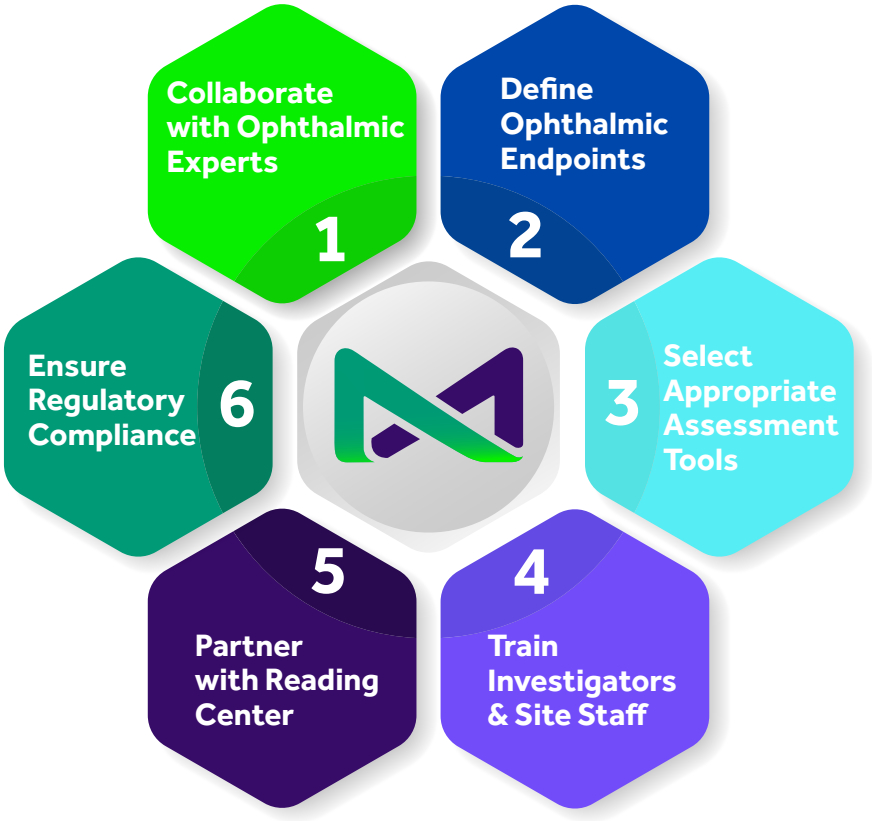
MERIT INFO SHEET

6 Steps for Selecting Ophthalmology Safety Endpoints in Non-Ophthalmology Clinical Trials

What if your company's early meetings with the FDA to review your preclinical data have indicated a need for ophthalmology safety endpoints in your upcoming non-ophthalmology clinical trial? What should your next steps be?



1 Collaborate Early with Ophthalmic Experts:

Collaborate with ophthalmologists and other specialists in the field to enhance the ophthalmic expertise within your trial team.

MERIT provides transparent communication and prompt access to our in-house team of ophthalmic experts (including several board-certified ophthalmologists).

2 Define Ophthalmic Endpoints:

Clearly define the ophthalmic endpoints you want to assess. These could include visual acuity, intraocular pressure, retinal function, and other relevant measures. Consult with ophthalmologists and other experts to determine the most appropriate endpoints for your specific trial.

Our insightful experts can help guide your selection of the right ophthalmic endpoints for your study.

3 Select Appropriate Assessment Tools:

Choose validated and standardized tools for assessing ophthalmic endpoints. This may include visual acuity assessments such as ETDRS Best Corrected Visual Acuity (BCVA) as well as imaging techniques like optical coherence tomography (OCT) and fundus photography (FP).

MERIT's comprehensive portfolio of ophthalmic endpoint services include BCVA and other visual acuity assessments. Our imaging modalities include not only common endpoints such as OCT and FP, but less common offerings such as specular microscopy and microperimetry.

4 Train Investigators and Site Staff:

Ensure that investigators and site staff are adequately trained on the use of the ophthalmic assessments and measurement tools via the MERIT certification process. Standardization of procedures is crucial for consistency across different trial sites.

MERIT's clinical operations team ensures the readiness of sites for study start up by providing detailed image acquisition procedures and instructions to sites. Our standardized site and technician certification processes support consistency across trial sites.

5 Partner with Reading Center to Reduce Variability:

Implement robust data management procedures to ensure the accuracy and integrity of ophthalmic endpoint data. Consider using centralized reading centers for image-based assessments to reduce data variability.

MERIT's over 10 years of experience as an ophthalmology independent reading center (IRC) supporting Phase I through IV clinical trials provides you with the domain expertise you need to assure high-quality, consistent data review and interpretation of your ophthalmic endpoint data.

6 Ensure Regulatory Compliance:

Stay informed about regulatory requirements related to ophthalmic assessments in clinical trials. Comply with relevant guidelines to facilitate successful trial conduct.

Through imaging protocol standardization using imaging charters and SOPs, IRCs like MERIT empower valid comparison of outcomes across multiple timepoints and help provide a pathway to regulatory approval.

MERIT

Your Clinical Endpoint Expert

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.

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