

Reading Centers in Clinical Trials: The CRO Perspective

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Reading Centers can bring objectivity to eligibility and outcome measure assessment in ophthalmic clinical trials. A CRO must consider how the measurements from the Reading Center impact the operational aspects of the study and carefully plan for communications, timely receipt and monitoring of gradings, format of data, and on going quality assurance. Important topics for consideration before trial commencement include: insuring a standard protocol for grading and initial and ongoing training of graders is in place; evaluating whether the planned timing of receipt of grading impacts eligibility assessment and thus study timelines; the media by which images will be sent to the Reading Center and media the CRO will use to receive gradings; how images and gradings expected and received will be tracked and reported. Considerations during trial conduct include: expected turn around times from image acquisition at the site to delivery at the Reading Center to Reading Center grading time and transmission of data to the CRO, and impact of these time frames on data lock and data currency at the time of lock; assessment of quality via review of internal Reading Center outcomes measuring contemporaneous variability in grading and temporal drift; measures of overall variability in grading potentially resulting from photo to photo quality variability and subtle changes in disease status. Well planned collaborations between the Reading Center and the CRO can enhance the quality of a trial.