

## Potential Risks & Benefits of a Clinical Trial

Before participating in a study, it is important to be confident about your decision. Weigh your options and stay informed.

### Possible Benefits

- » Access to new treatments and drugs before they are released to the market
- » Help advance new treatments
- » Extra care, attention, and follow up provided by our trained and dedicated research professionals
- » Improvement in physical well-being and quality of life
- » Stipends, driving allowances, and other incentives

### Possible Risks

- » Treatment may be less effective, or the same as standard treatment available for you
- » Unpredictable, possibly serious side effects
- » Frequent follow up appointments/clinic visits
- » Complicated medical or treatment schedule

## About Colorado Retina

Colorado Retina is a fourteen physician, owned and led sub-specialty eye care practice providing medical and surgical care of vitreoretinal eye disease.

Colorado Retina provides comprehensive retinal treatment for age-related macular degeneration (AMD), diabetic retinopathy, retinal vascular disease, retinal detachments, ocular tumors, uveitis/inflammatory eye disease, inherited retinal degenerations and numerous other retinal conditions.

Our group of specialists have trained at world-renowned fellowship programs and continue to engage in academia, advocacy, volunteering, and education both nationally and abroad.

We are proud to be the largest retina practice in the Rocky Mountain region. We provide six service locations spanning across Denver Metro in modern offices integrated with ambulatory surgery centers to facilitate immediate care for patients with ocular emergencies. Our two satellite locations extend care to Colorado's Summit County and Goodland, Kansas.

### Apply for a Trial

**STEP ONE.** Visit our website, review the patient requirements, then apply for the study you are interested in joining.

**STEP TWO.** A Colorado Retina researcher will contact you about your enrollment status. Note, you must volunteer and give your consent in order to be able to join a trial.

### Contact Us

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COLORADO RETINA

CLINICAL  
RESEARCH  
DEPARTMENT



Leaders in Innovation

## Classifications of Trials

**RANDOMIZED.** A patient is assigned to one of two or more treatments by chance— like a coin toss—not by choice. Neither the treatment team nor the patient can choose which patient gets which treatment. The care of each patient is similar, regardless of which treatment he or she receives. If one group is doing much better than the other, the trial will be stopped early. At the end of the trial, treatment groups are compared to determine if a new treatment might be better than the standard of care.

**MASKED & UNMASKED.** In a masked study, the patient is unaware of which treatment they are receiving, but the research team does. In unmasked studies, both the patient and the research team are aware of the treatment being used.

**CONTROL GROUP.** In studies of a disease for which there is approved treatment available, this standard of care treatment is often used as the control. This treatment is used as control because we know how it is designed to effect the physiological systems of the body. Some patients will get the standard of care compound, and others will get the investigational compound, but neither the patient nor the research staff or physicians will not know which they are taking. The control treatment lets the research sponsor team see if the effect of a new treatment is better than the standard of care treatment. If an approved treatment exists for the disease being studied, at a minimum patients will receive such treatment, or else the study treatment, but no one will go untreated.

**OBSERVATIONAL.** Participants receive the same care or treatment as all other patients. The doctors observe and record how patients do over time. They may then compare these results with the results of patients treated in a different time or place.

## Phases of Trials

**PHASE 1.** A new drug or treatment is tested on a small number of volunteers for short periods of time. Researchers look for what dose of the drug works best and record any side effects linked with the drug. They also hope to find out how the body absorbs and reacts to the drug, and how long it stays in the body. Early phase trial emphasis is on dosing level and potential side effects.

**PHASE 2.** A drug with known effects is tested at specific doses to learn how it may be useful. These trials also look to see what other side effects might be expected. In these studies, patients usually take a medication for a longer period of time. How the body absorbs and reacts to the drug, and how long it stays in the body, are also tested. A phase 2 trial helps researchers learn more about how a treatment improves a condition.

**PHASE 3 & 4.** A new treatment is compared with a commonly used treatment or with no treatment at all. Some patients in the trial will get the new treatment. Some will get the usual treatment or a placebo. These studies test whether a new treatment is effective and how best to use new treatments in caring for patients. Most clinical trials you will be offered will be phase 3 or 4 studies. A member of your clinical-trials team will tell you which type of study or trial you can be enrolled in and what treatments you may or may not receive.

## Our Research Department

Colorado Retina Associates offers a robust, in-house clinical research program to all of our patients.

We participate in some of the most innovative research and clinical trials surrounding retina treatments, diagnosis, and cures for blindness.

At Colorado Retina, we believe that ongoing research into disease states and treatments is a vital part of improving our patients' well-being

We are committed to participating in cutting-edge research, allowing our patients to have access to the latest treatments and drug options, while furthering scientific developments and changing the future of retina.

## What is a Clinical Trial?

Clinical trials are essential in advancing medical knowledge and result in developing new ways to prevent, detect, or treat disease.

## Goal of a Clinical Trial

The goal of a clinical trial is to determine if a new test or treatment is safe and effective.

Trials can also confirm if established treatments are equal to or better than new ones.

At Colorado Retina we have been involved with hundreds of clinical research trials that have significantly advanced our understanding of eye disease and have made numerous new treatments available to our patients.

Our goal is to ultimately improve the health and quality of life of our patients, and research is one of the many ways we seek to achieve that.