

## MODULE 10.0

### Clinical Studies and Treatment Data: Introduction

**C**linical trials and evidence-based results are vital in setting the standard of care for the ophthalmology practice. Short-term patient outcomes in clinical practice may be misleading. Viewing outcomes through clinical trial results may better reflect the long-term outcomes for patients with diabetic eye diseases.

In this module you will learn about several clinical studies that are shaping the care pathways for patients with diabetic eye diseases including DR and DME:

- READ-2
- RESOLVE
- FAME
- BOLT
- DRCR.net Protocol I
- CHAMPLAIN
- RIDE/RISE
- PLACID
- MEAD
- RESTORE
- VIVID/VISTA
- DRCR.net Protocol T
- Ongoing Studies

#### Introduction

Although clinical research addresses pertinent efficacy issues faced daily in medical clinics, interpreting clinical trial result data is multifactorial and can be challenging to implement into private practice. This relates to the differences between patients enrolled in the trial and the individual patients being treated in clinical practice.

In the past decade anti-vascular endothelial growth factor (anti-VEGF) therapies have made a substantial impact on the prevention of vision loss and the overall improvement of vision for patients with diabetic retinopathy (DR) or diabetic macular edema (DME). Unfortunately, not all patients respond as well to anti-VEGF therapies as others. An estimated 40%-50% of patients who have been treated with anti-VEGF therapy do not have acceptable visual improvements and/or resolution of retinal swelling. There are still improvements to be made in anti-VEGF therapies for the treatment of diabetic eye diseases. These improvements depend on the results of clinical research.

Clinical trials performed in the past decade have changed the standard of care for patients with DR and DME. Trial results have proven the effectiveness of anti-VEGF drugs over previous methods of treatments for diabetic eye diseases, including laser therapy, corticosteroid treatments, and vitrectomy surgery. Results from clinical trials, such as the DRCR.net Protocol T, are aiding in the comparison of anti-VEGF therapies and the understanding of relative efficacy among approved drugs, including aflibercept, bevacizumab, and ranibizumab.