

## A Phase III trial of a novel monoclonal antibody against Diabetic macular edema

### Situation:

An interventional trial of Phase III, aimed at treating problems of diabetic macular edema of patients where the usual laser therapy could not be applied due to proximity between edema site and optic nerve.

### Challenges:

- The IP was being investigated for diabetic macular edema for the first time
- The management of the clinical trial was complex since the study was co-managed by an industry-academia partnership
- Lack of awareness about conduct & organization of clinical trials amongst the PI

### SIRO Strategy:

- SIRO team clearly defined the responsibilities of the PI & its own team to avoid conflict and overlap
- All the relevant study documents were composed perfectly & within specified timelines in order to expedite the regulatory process

### Result:

- The entire clinical trial went off without any complication due to the co-operation of the SIRO team & the PI
- Regulatory approval was granted quickly & without any delays