Completed Clinical Research Trials Prema Abraham, M.D.

AMD Studies

2010 – Present	Principal Investigator: "A Phase 2, randomized, double-masked, controlled trial to establish the safety and efficacy of intravitreous injections of E10030 (anti-PDGF pegylated aptamer) given in combination with Lucentis in subjects with neovascular age-related macular degeneration". OPHTHOTECH CORP., New York, New York	
2010 – Preset	Principal Investigator: "An Open-Label, Long-term, Safety and Tolerability Extension Study of Intravitreal VEFG Trap-Eye in Neovascular Age-Related Macular Degeneration". Regeneron Pharmaceuticals, Tarrytown, New York.	
2009 – Present	Principal Investigator: "A Phase 3, double-masked, multicenter, randomized, active treatment-controlled study of the efficacy and safety of 0.5 mg and 2.0 mg Ranibizumab administered monthly or on an as-needed basis (PRN) in patients with subfoveal neovascular age-related macular degeneration". Genentech, Inc., South San Francisco, California	
2009 – Present	Sub-Investigator: "Ranibizumab for treating submacular vascularized PED – A prospective pilot study". Southern California Desert Retina Consultants, Palm Springs, California.	
2007 – Present	Principal Investigator: "A Randomized, Double Masked, Active Controlled Phase 3 study of the efficacy, safety, and tolerability of repeated doses of intravitreal VEGF Trap in subjects with neovascular age-related macular degeneration". Regeneron Pharmaceuticals, Tarrytown, New York.	
2007 – Present	Principal Investigator: "An open-label, long-term, safety, and tolerability study of intravitreal VEGF Trap-eye in subjects with neovascular age-related macular degeneration". Regeneron Pharmaceuticals, Tarrytown, New York.	
2007 – 2009	Principal Investigator: "A Phase 3, randomized, double-masked, parallel-assignment study of intravitreal bevasiranib sodium, administered every 8 or 12 weeks as maintenance therapy following three injections of Lucentis® compared to	

Lucentis® monotherapy every 4 weeks in patients with exudative age-related macular degeneration (AMD)". Opko Helath, Inc., Miami, Florida.

2007 - 2009

Principal Investigator: "A phase 1, open-label study to investigate the safety, tolerability, and pharmacokinetic profile of single and repeated doses of JSM6427 following administration by intravitreal injection in patients with neovascular age-related macular degeneration". Jerini Ophthalmic, New York, New York

2006 - 2010

Principal Investigator: "A 24-month randomized, double-masked, multi-center, phase IIIb study assessing safety and efficacy of verteporfin (Visudyne®) photodynamic therapy administered in conjunction with ranibizumab (Lucentis™) versus ranibizumab (Lucentis™) monotherapy in patients with subfoveal choroidal neovascularization secondary to age-related macular degeneration", Novartis Pharmacueticals Corporation, East Hanover, New Jersey.

2006 - 2008

Principal Investigator: "A Phase IV, open-label, multi-center, trial of maintenance intravitreous injections of Macugen® (Pegaptanib Sodium) given every 6 weeks for 48 weeks in subjects with subfoveal neovascular age-related macular degeneration (AMD) initially treated with a different modality resulting in maculopathy improvement", OSI Eyetech, New York, New York.

2006 - 2007

Principal Investigator: "A Randomized, Double-Masked, Multicenter, Phase I/II study of the safety of PTK787 administered in conjunction with Photodynamic Therapy with Visudyne® to patients with predominantly classic, minimally classic, and occult with no classic Subfoveal CNV secondary to Age-Related Macular Degeneration", Novartis Pharmaceuticals Corporation, East Hanover, New Jersey.

2006 - 2008

Principal Investigator: "A Randomized, Controlled Study of the Safety, Tolerability, and Biological Effect of Repeated Intravitreal Administration of VEGF Trap in Patients with Neovascular Age-Related Macular Degeneration", Regeneron Pharmaceuticals, Tarrytown, NY

2006 - 2007

Principal Investigator: "A Phase I, Open-Label, Single-Dose, Sequential, Dose-Escalation Study of

Intravitreal Administration of AG-013958 in Subjects with Subfoveal CNV associated with Age-Related Macular Degeneration", Pfizer, Inc. San Diego, CA.

2005 – 2007 Principal Investigator: "A Phase IIIb, Single-Masked, Multicenter, Randomized Study to Evaluate the Safety and Tolerability of Ranibizumab in Naïve and Previously Treated Subjects with Choroidal Neovascularization (CNV) Secondary to Age-Related Macular Degeneration", Genentech, Inc., South San Francisco, CA.

Principal Investigator: "A Phase II, Randomized, Double-Masked, Controlled, Dose Comparison Study of Cand 5 for Intravitreal Injection for the Treatment of Subfoveal Choroidal Neovascularization Associated with Wet Age-Related Macular Degeneration", Acuity Pharmaceuticals, Philadelphia, PA.

Principal Investigator: "An Open-Label, Multicenter Extension Study to Evaluate the Safety and Tolerability of Ranibizumab in Subjects with Subfoveal Choroidal Neovascularization Secondary to Age-Related Macular Degeneration who have completed the treatment phase of a Genentech-Sponsored Ranibizumab Study", Genentech Inc., So San Francisco, CA.

Principal Investigator: "Interval Dose Evaluation of Anecortave Acetate ", Alcon Research, Ltd, Fort Worth Texas

Principal Investigator: "Anti-Human VEGF Antibody Fab for the Treatment of Subfoveal Choroidal Neovascularization in AMD 3 Monthly Dosing, BioTherapeutic Unit-Genentech, Inc., South San Francisco, California

Principal Investigator: "Anecortave Acetate Risk-Reduction Trial", Alcon Research, Ltd, Fort Worth, Texas

Principal Investigator: "Anti-VEGF Antibody for the Treatment of Predominantly Classic Choroidal Neovascularization in AMD", BioTherapeutic Unit, Genentech, Inc., South San Francisco, California

2005 – 2007

2005 - 2009

2005 – 2007

2004 - 2007

2004 – 2008

2003 - 2006

2003 - 2006

Principal Investigator: "Minimally Classic/Occult Trial of AntiVEGF Antibody RhuFab V2 In the Treatment of Neovascular AMD", BioTherapeutic Unit, Genentech, Inc., South San Francisco, California

DME Studies

2010 - Present

Principal Investigator: "Ranibizumab for Edema of the macula in Diabetes: Protocol 3 with High Dose – the READ 3 study". Juvenile Diabetes Research Foundation, New York, New York

2009 - Present

Principal Investigator: "A phase 2 prospective, randomized, multi-center, diabetic macular edema dose ranging, comparator study evaluating the efficacy and safety of PF-04523655 versus laser therapy (DEGAS)". Pfizer – LaJolla Laboratories, San Diego, California

2007 - 2010

Principal Investigator: "A 52 week, masked, multicenter, randomized, controlled trial to assess the safety and efficacy of Dexamethasone Posterior Segment Drug Delivery System (DEX PS DDS) Applicator system in combination with laser photocoagulation compared with laser photocoagulation alone in the treatment of subjects with Diffuse Diabetic Macular Edema." Allergan, Irvine, California.

2007 - Present

Principal Investigator: "A phase 3, double-masked, multi-center, randomized, sham injection — controlled study of the efficacy and safety of Ranibizumab injection in subjects with clinically significant macular edema with center involvement secondary to diabetes mellitus". Genentech, Inc., San Francisco, California

2006 - Present

Principal Investigator: "Ranibizumab for Edema of the macula in Diabetes: A phase II study (The READ-2 Study)", Johns Hopkins University, Baltimore, MD.

2006 - Present

Principal Investigator: "A Randomized, Double-Masked, Parallel Group, Multi-center, Dose-Finding Comparison of the Safety and Efficacy of ASI-001A 0.5 μ g/day and ASI-001B 0.2 μ g/day Fluocinolone Acetonide Intravitreal Inserts to Sham Injection in Subjects with Diabetic Macular Edema", Alimera Sciences, Inc and pSivida Inc., Alpharetta, Georgia.

	2006 – 2008	Principal Investigator: "Open-Label treatment for Patients Completing Study B7A-MC-MBCM", Eli Lilly and Company, Indianapolis, Indiana.
	2005 – 2008	Principal Investigator: "A Randomized Trial Comparing Intravitreal Triamcinolone Acetonide and Laser Photocoagulation for Diabetic Macular Edema", Diabetic Retinopathy Clinical Research Network.
	2005 – 2008	Principal Investigator: "Evaluation of Vitrectomy for Diabetic Macular Edema", Diabetic Retinopathy Clinical Research Network.
	2006 – 2007	Principal Investigator: "A Phase II, Pharmacokinetic, Randomized, Double-Masked, Controlled, Dose Comparison Study of Cand5 for Intravitreal Injection for the Treatment of Diabetic Macular Edema", Acuity Pharmaceuticals, Philadelphia, PA.
	2004 – 2008	Principal Investigator: "Reduction in the Occurrence of Center-Threatening Diabetic Macular Edema", Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, Indiana
	2001 – 2005	Principal Investigator: "Protein Kinase C β Inhibitor – Diabetic Retinopathy Study 2", Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, Indiana.
RVO Studies	2009 – Present	Principal Investigator: "A randomized, double masked, controlled phase 3 study of the efficacy, safety and tolerability of repeated intravitreal administration of VEGF Trap-Eye in subjects with macular edema secondary to central retinal vein occlusion". Regeneron Pharmaceuticals, Tarrytown, New York
	2008 – 2010	Principal Investigator: "An open-label, multicenter extension study to evaluate the safety and tolerability of Ranibizumab in subjects with Choroidal Neovascularization (CNV) secondary to age-related macular degeneration (AMD) OR macular edema secondary to retinal vein occlusion (RVO) who have completed the treatment phase of a Genentech-Sponsored Ranibizumab study." Genentech, Inc. South San Francisco, California

2007 - 2008

Principal Investigator: "A six-month, phase 3, multicenter, masked, randomized, sham-controlled trial to assess the safety and efficacy of 700 ug and 350 ug Dexamethasone posterior segment drug delivery system (DEX PS DDS) applicator system in the treatment of patients with macular edema following central retinal vein occlusion or branch retinal vein occlusion". Allergan, Irvine, California.

2007 - 2010

Principal Investigator: "A phase 3, multicenter, randomized, sham-injection controlled study of the efficacy and safety of Ranibizumab injection compared with sham in subjects with macular edema secondary to branch/central retinal vein occlusion". Genentech, Inc., San Francisco, California

Other Studies

2010 - Present

Principal Investigator: "A randomized, shaminjection controlled, double-masked, multicenter trial of Ocriplasmin intravitreal injection for treatment of focal Vitreomacular Adhesion in subjects with Exudative Age-Related Macular Degeneration (AMD)". ThromboGenics Inc., New York, New York

2009 - 2010

Principal Investigator:"A randomized, placebo controlled, double-masked, multicenter trial of microplasim intravitreal injection for non-surgical treatment of focal vitreomacular adhesion". ThromboGenics Inc., New York, New York

2008 - Present

Principal Investigator: "A randomized, double-blind placebo-controlled study to evaluate the ocular safety of SCH 530348 in subjects participating in the Schering-Plough P04737 study (TRA secondary prevention ocular safety study)". Schering-Plough Research Institute, Kenilworth, New Jersey

2006 - 2009

Sub-Investigator: "A phase 1 Study of the Safety and Efficacy of multiple intravitreal injections of Ranibizumab in subjects with choroidal neovascularization secondary to causes other than age-related macular degeneration". Jeffery Heier, MD, Ophthalmic Consultants of Boston, Boston, MA.

2006 - 2007

Principal Investigator: "Clinical Evaluation of the Safety of Next Generation Ophthalmic Irrigating

During Surgery for Removal of Epimacular Membrane Vitrectomy", Alcon Research, Ft. Worth, Texas. 1999 - 2000"The Family (Genetic) Study of Macular Degeneration, J. Seddon, J., and Abraham, P., Preceptor, Harvard Medical School, Boston, Massachusetts. 1992 - 1994"Induced Refractive Change Following Scleral Buckling Procedures", Brinton, G.S. and Abraham, P., Preceptor, University of Utah, Department of Ophthalmology, Salt Lake City, Utah. 1986 - 1988"Chemical Induction of Locomotion in the In Vitro Brainstem-Spinal Cord Preparation", Garcia-Rill, E. and Abraham, P., Preceptor, Department of Neuroanatomy, University of Arkansas School of Medicine, Little Rock, Arkansas. "Development of Pedunculopontine Nucleus: I. In 1986 - 1987Vivo, Garcia-Rill, E., Preceptor, Department of Neuroanatomy, University of Arkansas School of Medicine, Little Rock, Arkansas. 1982 - 1983"Determination of Bound Iodine in Human Milk. Market Milk and Commercial Infant Formulae",

Solution (NGOIS) Compared to BSS PLUS for Use

Anderson, H., Preceptor, University of Missouri

Research Reactor, Columbia, Missouri.