ACTVE INTERVENTIONAL CLINICAL TRIALS - 03/01/2015

Principal Investigator	Study Title and Sponsor	Study Description
Cornea and External Disease Service		
Li, Jennifer	A Prospective, Multicenter Post-Approval Study (PAS) of VisionCare's Implantable Miniature Telescope (by Dr. Isaac Lipshitz) in Patients with Bilateral Severe to Profound Central Vision Impairment Associated with End-Stage Age-Related Macular Degeneration (Protocol IMT-PAS-01) (VisionCare Ophthalmic Technologies)	To evaluate the safety of the Implantable Miniature Telescope (intraocular telescope) for the treatment of bilateral severe to profound vision impairment due to endstage age-related macular degeneration under commercial conditions following U.S. market approval. To further assess the safety of the intraocular telescope as measured by the proportion of patients who within 5 years after implantation experience persistent vision-impairing corneal edema (corneal edema leading to a persistent loss of best corrected distance visual acuity [BCDVA] > 2-lines from pre-surgery baseline level).
Glaucoma Service		
Brandt, James D.	Primary Tube Versus Trabeculectomy (PTVT) Study (Dept. of Ophthalmology & Vision Science in collaboration with Bascom Palmer Eye Institute)	To determine if a trabeculectomy with mitomycin C or Baerveldt implant surgery works better with fewer complications for subjects with inadequately controlled glaucoma undergoing their first incisional ocular surgery.
Brandt, James D.	Baerveldt Plate Area Comparison (BPAC) (Dept. of Ophthalmology & Vision Science in collaboration with Johns Hopkins Hospital and Glaucoma Research Network)	To compare the safety and efficacy of the 250 mm^2 and 350 mm^2 Baerveldt glaucoma implants in subjects who have had previous ocular surgery.
Brandt, James D.	An Open-Label Extension (OLE) Study to Evaluate the Safety of the ForSight Vision5 Bimatoprost Ocular Insert in Subjects with Open-Angel Glaucoma or Ocular Hypertension Who Have Completed Study FSV5-002 (FSV5-003 OLE - ForSight VISION5, Inc.)	To evaluate the safety, intraocular pressure (IOP) lowering effect and comfort of the investigational Bimatoprost Ocular Insert when administered for 13 months in subjects with open-angle glaucoma or ocular hypertension who have completed study FSV5-002.

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Lim, Michele C.	Evaluation of Optic Nerve Structure and Function in Patients with Kerotoprosthesis (Department of Ophthalmology & Vision Science)	To better understand how to monitor patients with a Boston keratoprosthesis (K-pro) for optic nerve damage from glaucoma through optic nerve photography, spectral-domain OCT, kinetic visual fields, and Humphrey visual fields. Patients with a K-pro are at high risk for developing glaucoma and it is difficult to measure eye pressure (IOP) in these patients due to the rigid plastic material from which the K-pro is made. Therefore, finding other measures to evaluate patients with a keratoprosthesis are necessary.
Pediatric Ophthalmology Service		
O'Hara, Mary A.	INTERMITTENT EXOTROPIA STUDY 2 (IXT2): A Randomized Clinical Trial of Observation versus Occlusion Therapy for Intermittent Exotropia (National Eye Institute / Jaeb Center for Health Research)	To determine the effectiveness of occlusion (covering one eye) for the treatment of Intermittent Exotropia (misaligned eyes) among patients aged 1 to < 11 years; and to determine the natural history of Intermittent Exotropia among patients aged 1 to < 11 years who have baseline near stereoacuity of 400 arcsec or better by Preschool Randot stereotest.
O'Hara, Mary A.	Pediatric Cataract Surgery Outcomes Registry (CO2) (National Eye Institute / Jaeb Cener for Health Research)	To enroll individuals between birth and 13 years of age who have undergone cataract surgery in at least one eye into a data registry over a 3-year period. It is anticipated that 1000 children will be enrolled. Specific Aims: • To define the occurrence and risk factors of complications following cataract surgery after a minimum of 5 years. • To provide visual acuity outcome data for unilateral and bilateral cataract surgery, with and without IOL implantation.
Retina Service		

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Principal Investigator	Study Title and Sponsor	Study Description
Morse, Lawrence S.	A Phase III, Multinational, Multicenter, Randomized, Double-Masked, Study Assessing the Safety and Efficacy of Intravitreal Injections of DE-109 (three doses) for the Treatment of Active, Non-Infectious Uveitis of the Posterior Segment of the Eye (Santen, Inc.)	To test how well three different strengths of DE-109 (containing the drug sirolimus) work to treat active non-infectious posterior, intermediate or pan-uveitis.
Morse, Lawrence S.	Multi-Center, Randomized, Single Masked Phase 2 Study of Intravitreal Injections of Sirolimus in the Treatment of Geographic Atrophy Associated with Age-Related Macular Degeneration (National Eye Institute, sponsor; Santen, Inc. funding - Coordinating Center: The EMMES Corporation)	To determine the rate of change in area of Geographic Atrophy in the study eye. Eligible participants will be randomized to receive either an intravitreal injection of the study drug sirolimus or a sham treatment (subconjunctival injection of lidocaine).
Park, Susanna S.	Phase 1/2 Randomized Prospective Double-Blinded Trial Comparing Intravitreal Administration of Inhibitors of Vascular Endothelial Growth Factor Combined with Proton Beam Irradiation versus Intravitreal Administration of Vascular Endothelial Growth Factor Combined with Sham Irradiation in Treating Exudative Age-related Macular Degeneration (Investigator-Initiated; supported by Department of Ophthalmology & Vision Science Gift Account)	To test the hypothesis that low dose proton beam irradiation combined with intravitreal administration of inhibitor of vascular endothelial growth factor (anti-VEGF) is safe and more effective than treatment with anti-VEGF alone in treating exudative age-related macular degeneration (eAMD). Specifically, the Primary Objective of this study is to determine the safety and efficacy of proton beam radiation combined with ranibizumab (Lucentis) or bevacizumab (Avastin) in treating patients with exudative AMD.
Park, Susanna S.	A Pilot Clinical Trial of the Feasibility and Safety of Intravitreal Autologous Adult Bone Marrow Stem Cells in Treating Eyes with Vision Loss from Retinopathy (Investigator-initiated; supported by Department of Ophthalmology & Vision Science Gift Account)	To investigate the feasibility and safety of intravitreal autologous Bone Marrow Stem Cell therapy in treating people with irreversible vision loss from retinal degenerative conditions or retinal vascular disorders (dry age-related macular degeneration, retinitis pigmentosa, retinal vein occlusion, hereditary maculopathy or diabetic retinopathy). Fifteen subjects with vision loss that meet the inclusion and exclusion criteria of this study will be injected intravitreally with autologous stem cells derived from their own extracted bone marrow.

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Principal Investigator	Study Title and Sponsor	Study Description
Park, Susanna S.	Study of COmparative Treatments for REtinal Vein Occlusion 2 (SCORE2): a multicenter, prospective, randomized non-inferiority trial of eyes with macular edema secondary to central retinal vein occlusion, comparing intravitreal bevacizumab every 4 weeks with intravitreal aflibercept every 4 weeks. Short Title: Study of Comparative Treatments for Retinal Vein Occlusion 2 (SCORE2) (National Eye Institute/Penn State University)	To compare the drugs aflibercept (Eylea®) and bevacizumab (Avastin®) for treatment of macular edema (swelling in the center of the retina) due to central retinal vein occlusion (CRVO). Aflibercept is a drug that has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of macular edema due to CRVO. Bevacizumab is a drug that has been approved by the FDA for the treatment of some types of cancer but it has not been approved for use in the eye. However, since 2006, bevacizumab has been used to treat a wide variety of eye problems, including CRVO. Participants with a good response for first 6 months treatment will continue the study treatment assigned to randomly for another 6 months. Participants who have a poor response to randomly assigned treatment of aflibercept may receive an injecton(s) of dexamethasone. Participants who have a por respnse to randomly assigned treatment of bevacizumab may receive injections of aflibercept or other anti-VEGF treatment
Morse, Lawrence S.	A Phase III, Multicenter, Randomized, Double-Masked, Sham-Controlled Study to Assess the Efficacy and Safety of Lampalizumab Administered Intravitreally to Patients with Geographic Atrophy Secondary to Age-Related Macular Degeneration – Protocol GX29185/SPECTRI (Genentech/F. Hoffmann-La Roche Ltd)	To assess the efficacy and safety of 10-mg lampalizumab administered by intravitreal injections every 4 weeks (Q4W) or every 6 weeks (Q6W) relative to sham control for the treatment of Geographic Atrophy secondary to Age-Related Macular Degeneration. Efficacy, safety, and PK will be evaluated in CFI profile biomarker-positive and CFI profile biomarker-negative patients.
Visual Science and Advanced Retinal Imaging Laboratory		
Werner, John S.	Ophthalmic Imaging Using Adaptive Optics and Optical Coherence Tomography; National Institute for Aging & National Eye Institute	To learn more about retinal structure by using advanced technology to image both normal eyes and eyes showing one of various diseases being studied (retinal degeneration, optic nerve degeneration, etc.)

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Werner, John S.	Temporal Impulse Response Changes Across the Life Span; National Institutes of Health	To learn more about age-related changes in the ability to detect flicker or movement in people with normal eyes
Werner, John S.	Age-Related and Disease-Related Changes in the Photopic and Scotopic Full-Field and Multifocal ERGs; National Institutes of Health	To learn more about how the response of the retina changes with age and with macular degeneration