



# JAEB CENTER FOR HEALTH RESEARCH 2025 ANNUAL REPORT

## **Mission Statement:**

*To expand scientific knowledge and improve public health  
by designing and conducting world-class clinical trials  
and epidemiologic research.*

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## Overview

The Jaeb Center for Health Research (JCHR) enters its 33<sup>rd</sup> year with a continued commitment to advancing public health through world-class clinical research and data-driven science. This report provides an overview of our research achievements over the past year.

In 2025, JCHR continued its reach across high-impact therapeutic areas including diabetes, ophthalmology, and cystic fibrosis. The 2025 research portfolio reflects not only the breadth of JCHR's expertise but also the increasing complexity of studies entrusted to JCHR by federal agencies, industry partners, foundations, and international collaborators.

In 2025, JCHR was actively engaged in 61 clinical studies.

JCHR's research efforts focused on three main therapeutic areas:

- **Diabetes Research:** A multitude of clinical trials and observational studies involved research in type 1, type 2, and gestational diabetes, encompassing pediatric and adult populations including maternal-fetal health outcomes. Many studies focused on advancing technology-driven diabetes management with artificial pancreas systems, insulin pumps, and continuous glucose monitors (CGMs), while others involved the assessment of growing adjunct therapy use in diabetes care as well as interventional strategies to preserve endogenous insulin production, utilize inhaled insulin, or leverage enhanced patient and caregiver education including around exercise regimens to improve glucose control.
- **Eye Disease Research:** JCHR continued its role as a coordinating center for three major networks as well as individual eye disease studies:
  - ◆ The DRCR Retina Network, investigating diabetic retinopathy, age-related macular degeneration, and other retinal diseases.
  - ◆ The Pediatric Eye Disease Investigator Group (PEDIG), focusing on a wide range of childhood eye conditions.
  - ◆ The Foundation Fighting Blindness Consortium, dedicated to studying rare retinal diseases.

Additionally, JCHR is currently coordinating a study on long-term outcomes following corneal transplantation.

- **Cystic Fibrosis Research:** JCHR's growing research portfolio includes a trial investigating use of the bionic pancreas system to manage cystic fibrosis-related diabetes as well as observational studies seeking to better characterize other physiological and metabolic complications of cystic fibrosis. Key studies examined the impact of nutrition, muscle strength, and glucose monitoring technologies on lung function and overall health outcomes in individuals with cystic fibrosis.

During 2025, JCHR investigators and collaborators contributed an impressive body of peer-reviewed research, resulting in 53 publications, manuscripts and scientific presentations, culminating in 51 publications, including in the *New England Journal of Medicine* and *JAMA*, and 58 presentations at national and international meetings.

In terms of funding, JCHR secured grants from leading organizations, including the National Institutes of Health (6), Helmsley Charitable Trust (7), Breakthrough T1D (5), Foundation Fighting Blindness (6), Cystic Fibrosis Foundation (4), Food and Drug Administration (1), and National Institute for Health and Care Research (1).

Collaborations with 14 additional funding partners spanned 21 studies, including 11 investigator-initiated studies, underscoring JCHR's role as a trusted research partner. JCHR also self-funded one study and numerous statistical analysis projects using datasets from previously completed studies. Among approximately 2,705 entities receiving NIH funding in 2025, JCHR ranks in the top 8 percent. Out of approximately 59,500 NIH grants awarded in 2025, JCHR had the 108<sup>th</sup>- (top 0.18 percent) and 202<sup>nd</sup>- (top 0.34 percent) largest grants (source: Blue Ridge Institute for Medical Research, 2025).

Under the leadership of Executive Director Adam Glassman, JCHR's workforce continued to strengthen its expertise and scientific contributions. The organization benefits from a highly experienced staff whose longevity supports continuity, institutional knowledge, and a consistently high standard of research execution. The 2025 report highlights extensive involvement of JCHR team members in editorial boards, data and safety monitoring committees, grant review panels, and national and international research forums—reflecting the depth of scientific leadership across the organization.

As a home centric organization, JCHR continues to leverage a remote forward model that supports retention, flexibility, and recruitment of top talent while maintaining high operational efficiency.

In 2026, JCHR will continue to strengthen its position as a global leader in clinical research—expanding its project portfolio, elevating scientific contributions, and supporting multidisciplinary collaborations that shape the future of health care.

## Studies Active During 2025

### Notes:

- An *active* project is one in which (1) enrollment was open; (2) study participant data was collected; or (3) follow-up work was performed during the year.
- Studies marked with an asterisk did not include data collection during 2025; however, important supplementary work was accomplished.

## Network Studies

### DRCR Retina Network

- A Phase 2 Study Evaluating Short-Term Efficacy of Tonabersat (Xiflam) for Diabetic Macular Edema (Protocol AN)
- A Randomized Clinical Trial Evaluating Combination Faricimab + PRP versus Vitrectomy + Endolaser for Treatment of Proliferative Diabetic Retinopathy (Protocol AP)
- A Randomized Clinical Trial Evaluating Intravitreal Faricimab (6.0 mg) Injections or Fluocinolone Acetonide (0.19 mg) Intravitreal Implants versus Observation for Prevention of Visual Acuity Loss due to Radiation Retinopathy (Protocol AL)
- A Randomized Trial Evaluating Fenofibrate for Prevention of Diabetic Retinopathy Worsening (Protocol AF)
- Bevacizumab Treatment for Posterior Type 1 Retinopathy of Prematurity (ROP4, in collaboration with PEDIG)
- Diabetic Retinopathy and Changes in Lipid Metabolism (Protocol AFA)
- Genes in Diabetic Retinopathy Project (Protocol GEN)
- Home OCT-Guided Treatment versus Treat and Extend for the Management of Neovascular AMD (Protocol AO)
- Peripheral Diabetic Retinopathy (DR) Lesions on Ultrawide-Field Fundus Images and Risk of DR Worsening Over Time (Protocol AA)\*
- Randomized Trial Comparing Immediate versus Deferred Surgery for Symptomatic Epiretinal Membranes (Protocol AM)

- Use of Diagnostic Dataset to Enrich Recruiting for Clinical Trials for Diabetic Retinal Disease: A Feasibility Study (Protocol AQ)\*
- Vitreous Proteomics in Eyes with a Macular Hole (Protocol AJ)\*

### **Foundation Fighting Blindness Clinical Consortium**

- Gyrate Atrophy Ocular and Systemic Study (GYROS)
- Rate of Progression in EYS-related Retinal Degeneration (Pro-EYS)
- Rate of Progression in USH2A-related Retinal Degeneration Extension (RUSH2A)
- Rate of Progression of PCDH15-related Retinal Degeneration in Usher Syndrome 1F (RUSH1F)
- Universal Rare Gene Study: A Registry and Natural History Study of Retinal Dystrophies Associated with Rare Disease-Causing Genetic Variants (Uni-Rare)

### **Pediatric Eye Disease Investigator Group**

- A Randomized Clinical Trial to Evaluate Sequential versus Simultaneous Spectacles plus Patching (ATS22)
- A Randomized Placebo-controlled Trial of Spectacles with Highly Aspherical Lenslets or 0.05% Atropine to Slow Progression of Myopia in Children (MTS2)\*
- A Randomized Trial of Dichoptic Treatment for Amblyopia in Children 4 to 7 Years of Age (ATS23)
- A Randomized Trial of Dichoptic Treatment for Amblyopia in Children 8 to 12 Years of Age (ATS24)
- A Randomized Trial of Omega-3 Supplementation, Anti-Demodex Eyelid Cleanser, and Standard Eyelid Cleanser for Pediatric Chalazia (CH01)\*
- A Randomized Trial to Evaluate Low-Dose Atropine as Treatment for Myopia (MTS1)\*
- Bevacizumab Treatment for Posterior Type 1 Retinopathy of Prematurity (ROP4, in collaboration with DRRCR)
- Evaluation of Accommodative Behavior in Children With and Without Amblyopia (ATS21)\*
- Home Visual Acuity Testing (X06)\*
- Pediatric Uveitis Study: A Study of Uveitis in Children <18 Years of Age (UV1)\*
- Prospective Observational Study of Early-Onset Cerebral / Cortical Visual Impairment (CVI1)\*
- Randomized Trial of Full-Time Occlusion Therapy for Intermittent Exotropia in Children (IXT7)

## Non-Network Studies

### Diabetes Studies

- A 26-week Primary Treatment Phase, with 26-week Extension, Open-label, Randomized Clinical Trial Evaluating the Efficacy and Safety of Afrezza® Versus Rapid-acting Insulin Analog Injections, Both in Combination with a Basal Insulin, in Pediatric Subjects with Type 1 or Type 2 Diabetes Mellitus (INHALE-1)
- A Randomized Cross-Over Trial Evaluating Automated Insulin Delivery Technologies on Glycemic Outcomes and Quality of Life in Older Adults with Type 1 Diabetes (AIDE T1D)\*
- A Randomized Crossover Trial Evaluating the Effect of Inhaled Technosphere Insulin (Afrezza®) Versus Rapid Acting Analogue Insulin on Exercise-induced Hypoglycemia in Adults with Type 1 Diabetes Using Automated Insulin Delivery (INHALE-AIDEx)
- A Randomized Phase 1/2 Trial of Low Dose Anti-thymocyte Globulin (ATG) with Subsequent Adalimumab or Verapamil in New Onset Type 1 Diabetes (WAVE T1D)
- A Randomized Trial Evaluating the Efficacy and Safety of Control-IQ Technology in Adults with Type 2 Diabetes Using Basal-Bolus Insulin Therapy (2IQP)
- A Randomized, Placebo-controlled, Double-blinded Cross-over Study of the Pharmacologic Action of a GPR119 Agonist on Glucagon Counter-regulation during Insulin-induced Hypoglycemia in Type 1 Diabetes Mellitus (PHROG)
- A Single-arm Trial With an Innovative Automated Insulin Delivery System for Type 2 Diabetes (twiist-T2D)
- Accelerate Innovation of Diabetes Translation to Maximize Positive Impacts of Research on Population Health Through Activities and Core Services that Offer Specialized Expertise, Tools, Education, and Support (GCDTR)
- Breaking Health Care Disparities in Access to Advanced Diabetes Technologies in Children with Type 1 Diabetes
- Breakthrough T1D CGM in Prevention\*
- Care Partner-Coordinated Pilot of Tubeless Hybrid Closed Loop Insulin Delivery for Cognitively Impaired Older Adults with T1D (COPILOT)\*
- Closed Loop and Education for Hypoglycemia Awareness Restoration (CLEAR)
- CONTiNuous glucosE monitoring (CGM) in people wiTh type 2 diabetes not on insulin: The CONNECT Study (CONNECT)
- Educational Intervention to Support Diabetes Guidance for Exercise (EDGE)

- Evaluating the Efficacy and Safety of Inhaled Insulin (Afrezza®) Combined with Insulin Degludec Versus Usual Care in Adults with Type 1 Diabetes (INHALE-3)\*
- Hybrid Closed Loop and Verapamil for Beta Cell Preservation in New Onsets with T1D (CLVer)
- Open, Single Arm, Prospective, Multicenter Study of an Investigational Extended Wear Insulin Infusion Set During Home Use in People with Type 1 Diabetes (StadiSet)\*
- Pregnancy Data Repository to Assess Management of Type 1 Diabetes with Diabetes Technology (PRAM-T1D)
- Prospective Real-world Data Collection for the Bigfoot Unity Diabetes Management System (BURST)\*
- PROTECT Pregnancy Outcomes Using Continuous Glucose Monitoring TEChnology in Pregnant Women with Type 2 Diabetes: A Multicentre Randomised Controlled Trial of the Clinical and Cost-Effectiveness of Using Continuous Glucose Monitoring in Pregnant Women with Type 2 Diabetes (PROTECT)
- Safety and Efficacy of the Omnipod® 5 Automated Insulin Delivery System in Adults with Type 2 Diabetes (SECURE-T2D)\*
- Safety and Efficacy of the Omnipod® 5 SmartAdjust 2.0 System Compared to the Omnipod® 5 System in Individuals with Type 1 or Type 2 Diabetes (STRIVE)
- The Pediatric Artificial Pancreas Automated Initialization Trial (PEDAP-AI): A Pilot Study of AI Advisor-driven Pump Initiation and Parameter Adaptation in Young Children with Type 1 Diabetes\*
- The Safety and Efficacy of Rapid Acting Inhaled Technosphere Insulin (Afrezza) Compared with Subcutaneous Insulin to Achieve Pregnancy-Specific Postprandial Targets among Patients with Gestational Diabetes (INHALE-GDM)
- twiist Postmarket Surveillance Study in Adults and Youth with Type 1 Diabetes (twiistPS)
- Type 1 Diabetes EXercise Initiative Pediatric Study: The Effect of Exercise on Glycemic Control in Youth with Type 1 Diabetes (T1DexiP)\*
- Type 1 Diabetes EXercise Initiative: The Effect of Exercise on Glycemic Control in Type 1 Diabetes Study (T1DEXI)\*

## Eye Disease Studies

- Diabetes Endothelial Keratoplasty Study: Impact of Diabetes on Corneal Transplant Success and Endothelial Cell Loss (DEKS)

- Safety and Feasibility of Cultivated Autologous Limbal Epithelial Cell Transplantation in the Treatment of Limbal Stem Cell Deficiency (CALEC)

### **Cystic Fibrosis Studies**

- A Randomized Trial of the Insulin-only Bionic Pancreas in Cystic Fibrosis Related Diabetes (BPCFRD)
- Strength and Muscle Related Outcomes for Nutrition and Lung Functions in CF (STRONG-CF)
- Studying the Presence of CFRD Complications with Thoughtful Recruitment (SPeCTRuM)

### **Additional Studies**

- CGM for the Early Detection and Management of Hyperglycemia in Pregnancy (IMAGINE)

## Manuscripts and Presentations

**Note:**

JCHR employees appear in boldface type.

### DRCR Retina Network

#### Published and Accepted Manuscripts

- Ehlers JP, Josic K, Yordi S, Martin A, Srivastava SK, Sun JK, DRCR Retina Network. Assessment of baseline ultrawidefield fluorescein angiographic quantitative leakage parameters with ultrawidefield fundus features and clinical parameters in diabetic retinopathy in Protocol AA. *Ophthalmol Retina*. 2025 Mar;9(3):243-252. doi: 10.1016/j.oret.2024.08.015. Epub 2024 Aug 30.
- Hormel TT, **Beaulieu WT**, Wang J, Sun JK, Jia Y. Artificial intelligence versus rules-based approach for segmenting nonperfusion area in a DRCR Retina Network optical coherence tomography angiography dataset. *Invest Ophthalmol Vis Sci*. 2025 Mar 3;66(3):22. doi: 10.1167/iovs.66.3.22. PMID: 40062815; PMCID: PMC11905605.
- **Liu D**; **Maguire MG**; Jonna G; Jampol LM; Labriola LT; Martin DF; Sun JK; DRCR Retina Network. Association of patient age with response to anti-vascular endothelial growth factor agents for treatment of diabetic macular edema. *Retina*. Published online October 14, 2025. doi:10.1097/IAE.0000000000004707.
- Shen S, **Josic K**, Pak JW, Meuer SM, **Melia M**, Domalpally A, Sun JK, Blodi B; DRCR Retina Network. Long-term effects of Anti-VEGF therapy versus panretinal photocoagulation on retinal vessel caliber in eyes with proliferative diabetic retinopathy. *Ophthalmol Retina*. 2025 Apr 9:S2468-6530(25)00159-9. doi: 10.1016/j.oret.2025.03.027. Epub ahead of print. PMID: 40216022.
- Silva PS, **Liu D**, Aiello LP, **Melia M**, Sun JK; DRCR Retina Network. Diabetic retinopathy lesion types and distribution on ultrawide field imaging and the risk of disease worsening over time. *Retina*. 2025 Jan 1;45(1):44-51. doi: 10.1097/IAE.0000000000004263 (published).
- Tan TE, Ng YP, **Calhoun C**, Chung JQ, Yao J, Wang Y, Zhen L, Xu X, Liu Y, Goh RSM, Piccoli G, Vujosevic S, Tan GSW, Sun JK, Ting DSW. Detection of center-involved diabetic macular edema with visual impairment using multimodal artificial intelligence algorithms. *Ophthalmol Retina*. 2025 Apr 24:S2468-6530(25)00173-3. doi: 10.1016/j.oret.2025.04.016. Epub ahead of print. PMID: 40286985.

## Presentations

- Silva PS. Differences between DRSS grades on UWF-color and UWF-FA and association with risk of disease worsening over 4 years (Protocol AA). Presented at The Macula Society 48<sup>th</sup> Annual Meeting, Charlotte Harbor, FL, February 2025.
- Barkmeier AJ, Grigorian R, on behalf of the DRCR Retina Network. Refining diabetic retinopathy severity and risk of worsening based on ultrawide field fluorescein angiography. Presented at the 43<sup>rd</sup> Annual American Society of Retina Specialists Annual Meeting, Long Beach, CA, July-August 2025.
- Labriola LT. Association of patient age with response to anti-VEGF agents for treating DME. Presented at The Retina Society 58<sup>th</sup> Annual Scientific Meeting, Chicago, IL, September 2025.
- Silva PS. Differences between DRSS grades on UWF-color and UWF-FA and association with risk of disease worsening over 4 years (Protocol AA). Presented at The Retina Society 58<sup>th</sup> Annual Scientific Meeting, Chicago, IL, September 2025.
- Sun JK, on behalf of the DRCR Retina Network. Long-term effects of anti-VEGF therapy versus PRP on retinal vessel caliber in eyes with PDR. Presented at The Retina Society 58<sup>th</sup> Annual Scientific Meeting, Chicago, IL, September 2025.
- Baskin DE, Sun JK, Barkmeier AJ, Weng CY, Martin DF. 20+ years of DRCR retina trials: What every retina fellow and specialist needs to know. Presented at the Annual American Academy of Ophthalmology Meeting, Orlando, FL, October 2025.

## Foundation Fighting Blindness Clinical Consortium

### Published and Accepted Manuscripts

- Birch DG, Duncan JL, Samarakoon L, **Melia M**, Audo I, **Ayala AR**, Cheetham JK, Durham TA, Huckfeldt RM, Maldonado R, Michaelides M, Pennesi ME, Stingl K for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Progression of dark-adapted visual fields over 3 years in the rate of progression in USH2A-related retinal degeneration (RUSH2A) study. Invest Ophthalmol Vis Sci. 2025 Aug 1;66(11):27. doi: 10.1167/iovs.66.11.27. PMID: 40792671; PMCID: PMC12364011.

- Branham K, Samarakoon L, Audo I, **Ayala AR**, Cheetham JK, Daiger SP, Dhooge P, Duncan JL, Durham TA, Fahim AT, Huckfeldt RM, Hufnagel RB, Kohl S, Maldonado RS, **Melia M**, Michaelides M, Pennesi ME, Sahel JA, Sallum JMF, Singh MS, Sharon D, Stepien K, Jones K, Weng C for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Characterizing the genetic basis for inherited retinal disease: Lessons learned from the Foundation Fighting Blindness Clinical Consortium's gene poll. *Invest. Ophthalmol. Vis. Sci.* 2025;66(2):12. doi: 10.1167/iovs.66.2.12. PMID: 39908130; PMCID: PMC11804890.
- Duncan JL, **Maguire MG**, McDaniel LS, Doucet NR, Audo I, **Ayala AR**, Cheetham JK, Cheng P, Durham TA, Huckfeldt RM, Hufnagel RB, Jayasundera KT, Khan N, Malbin B, Maldonado RS, Michaelides M, Pennesi ME, Weng CY, Zmejkoski A, Aravind S, Ishikawa H, Birch DG for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Characterization of visual field loss over 4 years in the rate of progression in USH2A-related retinal degeneration (RUSH2A) study. *Am J Ophthalmol.* 2025 Aug;276:9-21. doi: 10.1016/j.ajo.2025.03.039. Epub 2025 Mar 27. PMID: 40157442.
- Parekh B, Peck-Dimit N, Duncan JL, Samarakoon L, Abalem MF, Andrews CA, Audo I, **Ayala AR**, Bradley C, Cheetham JK, Dagnelie G, Durham TA, Huckfeldt RM, Lacy GD, Malbin B, Michaelides M, Musch DC, Stingl K, Weng CY, Zmejkoski AZ, **Melia M**, Jayasundera KT for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Functional vision assessment over 4 years in USH2A using the veteran affairs low-vision visual functioning questionnaire. *Invest Ophthalmol Vis Sci.* 2025 May 1;66(5):39. doi: 10.1167/iovs.66.5.39. PMID: 40423621; PMCID: PMC12124157.
- Vincent A, Liang W, **Maguire MG**, Duncan JL, **Ayala AR**, Bernstein PS, Carroll J, Cheetham JK, Durham TA, Farsiu S, Hoyng CB, Huckfeldt RM, Jaffe GJ, Loo J, Pennesi ME, Sahel JA, Singh MS, Zemborain ZZ, Birch DG, Lad EM for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Natural history of microperimetry and optical coherence tomography in USH2A-retinopathy: A structure-function association study. *Am J Ophthalmol.* 2025 May 3;276:336-349. doi: 10.1016/j.ajo.2025.04.034. PMID: 40324556.

## Presentations

- Huckfeldt R, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Functional transition points: Assessing changes in visual field sensitivity with function-guided prespecification of points. Presented at The Macula Society 48<sup>th</sup> Annual Meeting, Charlotte Harbor, FL, February 2025.
- Birch D, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. FST background and data review. Presented at the European Reference Network Eye Diseases (ERN-EYE) meeting, Association for Research in Vision and Ophthalmology Annual Meeting, Salt Lake City, UT, May 2025.

- Duncan J, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Regulatory endpoints and trial design: REDI to inform clinical trials for retinal degenerations. Presented at the Retinal Therapeutics Summit, Salt Lake City, UT, May 2025.
- Duncan J, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Alternative endpoints. Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Salt Lake City, UT, May 2025.
- Huckfeldt R, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Strategies for evaluating, selecting, and improving endpoints. Presented at the European Reference Network Eye Diseases (ERN-EYE) meeting, Association for Research in Vision and Ophthalmology Annual Meeting, Salt Lake City, UT, May 2025.
- Huckfeldt R, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Regulatory endpoints and trial design for IRDs (REDI) working group: Ongoing efforts. Presented at the Ocular Diseases Forum 3, Washington, DC, May 2025.
- Huckfeldt R, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Considerations for clinical trial population for full-field stimulus testing. Presented at the Ocular Diseases Forum 3, Washington, DC, May 2025.
- **McDaniel L**, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. FST minimal clinically important difference. Presented at the European Reference Network Eye Diseases (ERN-EYE) meeting, Association for Research in Vision and Ophthalmology Annual Meeting, Salt Lake City, UT, May 2025.
- **McDaniel L**, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. FST minimal clinically important difference. Presented at the Ocular Diseases Forum 3, Washington, DC. May 2025.
- Zmejkoski A, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Correlation between static and semi-kinetic perimetry along the horizontal meridian in USH2A-associated retinitis pigmentosa: An analysis from the RUSH2A study. Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Salt Lake City, UT, May 2025.
- Birch DG, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Clinical endpoints in IRDs: the USA perspective. Presented at the 62<sup>nd</sup> Annual Symposium of the International Society for Clinical Electrophysiology of Vision, ISCEV, Utrecht, The Netherlands, June 2025.

- Huckfeldt RM, Birch DG, Duncan JL, Durham TA, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Endpoints and trial design. Presented at the Association for Research in Vision and Ophthalmology Special Interest Group, June 2025 (virtual).
- **Ayala AR**, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Role of full-field stimulus threshold in ophthalmologic therapeutic drug and biologics development. Presented at the FDA-sponsored hybrid meeting at Duke-Margolis Institute for Health Policy: Assessing Novel Efficacy Endpoints in Ophthalmologic Rare Disease Drug and Biologics Development, Washington, DC, September 2025.
- Pennesi ME, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Endpoints: What can we learn from inherited retinal degenerations? Presented at the Frontier Therapeutics in Retinal Degeneration Neuroscience School of Advanced Studies Challenge Workshop, Crans-Montana, Chetzeron, Switzerland, September 2025.
- Duncan JL, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. How can we show treatments are safe and effective in retinal degenerations? Presented at the American Academy of Ophthalmology Retina Subspecialty Day, Orlando, FL. October 2025.
- Sahel JA, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Lost in translation. Presented at the Frontier Therapeutics in Retinal Degeneration Neuroscience School of Advanced Studies Challenge Workshop, Crans-Montana, Chetzeron, Switzerland, October 2025.
- Singh M, Valle D, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Gyrate atrophy ocular and systemic (GYROS) study. Presented at FLORetina 2025, Florence, Italy, December 2025.

## Pediatric Eye Disease Investigator Group

### Published and Accepted Manuscripts

- **Beaulieu WT**, Repka MX, Pineles SL, **Chandler DL**, Pang Y, Kehler LAF, Jordan CO, Lee KA, Petersen DB, Hatt SR, Cotter SA, **Kraker RT**, Weise KK, Holmes JM. Does past myopia progression predict future progression? Invest Ophthalmol Vis Sci. (accepted).
- de Alba Campomanes AG, Repka MX, Hatt SR, **Sutherland DR**, Leske DA, Morrison DG, Fallaha N, **Melia BM**, **Kraker RT**, Cotter SA, Holmes JM. Myopic shift over five years following pediatric lensectomy with primary intraocular lens implantation. Ophthalmology. 2025;132(3):290-298.

- de Alba Campomanes AG, Repka MX, **Wu R**, Hatt SR, Young MP, McCourt EA, Colburn JD, **Beaulieu WT**, **Kraker RT**, Cotter SA, Holmes JM. Ophthalmic outcomes five years after lensectomy among children with Down syndrome. *J AAPOS*. 2025;29(4):104273. doi:10.1016/j.jaapos.2025.104273.
- Jenewein EC, Christiansen SP, **Zhu Y**, **Kraker RT**, Grigorian AP, Suh DW, Summers AI, Han S, Rahmani B, Connolly KS, Davis PL, Fisher JH, Javed YF, Kraus CL, Kurup SP, Martinson SR, Ollinger MC, Tauscher RG, Vricella M, **Beaulieu WT**, Pineles SL, Cotter SA, Holmes JM, Weise KK. A randomized clinical trial of full-time alternate patching therapy for intermittent exotropia in children. *Optom Vis Sci*. (accepted).
- Repka MX, **Sutherland DR**, Hatt SR, Rahmani B, Leske DA, Bothun ED, Young MP, Strominger MB, Tamkins SM, **Beaulieu WT**, **Kraker RT**, Holmes JM, Cotter SA. Effects of age at surgery and laterality of cataract on visual acuity 5 years after surgery in infants left aphakic. *Ophthalmology*. 2025;132(11):1284-1293. doi:10.1016/j.opthta.2025.06.022.
- Stahl ED, **Sutherland DR**, Repka MX, Hatt SR, Enyedi LB, Colburn JD, Yoon HH, Leske DA, **Kraker RT**, **Beaulieu WT**, Cotter SA, Holmes JM, Pineles SL, Weise KK. Visual outcomes and complications over 5 years following lensectomy for childhood traumatic cataract. *JAMA Ophthalmol*. 2025;143(12):1035-1042. doi:10.1001/jamaophthalmol.2025.4121.
- **Wu R**, Manny RE, Holmes JM, **Melia BM**, **Li Z**, Wallace DK, Birch EE, **Kraker RT**, Cotter SA. Validating rules for defining no improvement of visual acuity in childhood amblyopia. *Invest Ophthalmol Vis Sci*. 2025;66(1):4.

### Presentations

- Erzurum SA, on behalf of the Pediatric Eye Disease Investigator Group. Treatments for a chalazion in children 4 to <18 years of age. Presented at the American Association for Pediatric Ophthalmology and Strabismus Annual Meeting, Salt Lake City, UT, March 2025.
- Holmes JM, on behalf of the Pediatric Eye Disease Investigator Group. Does prior progression predict future change in myopia? Presented at the American Association for Pediatric Ophthalmology and Strabismus Annual Meeting, Salt Lake City, UT, March 2025.
- Raghuram A, on behalf of the Pediatric Eye Disease Investigator Group. Relationship between changes in axial length and spherical equivalent refractive error over 30 months in a randomized clinical trial of atropine 0.01% versus placebo eye drops. Presented at the American Association for Pediatric Ophthalmology and Strabismus Annual Meeting, Salt Lake City, UT, March 2025.

- Roberts TL, on behalf of the Pediatric Eye Disease Investigator Group. At-home visual acuity in children using a custom iPhone® application compared with in-office visual acuity testing using standardized amblyopia treatment study protocols. Presented at the American Association for Pediatric Ophthalmology and Strabismus Annual Meeting, Salt Lake City, UT, March 2025.
- Summers AI, on behalf of the Pediatric Eye Disease Investigator Group. Demographics of participants enrolled into Pediatric Eye Disease Investigator Group (PEDIG) studies of intermittent exotropia or amblyopia. Presented at the American Association for Pediatric Ophthalmology and Strabismus Annual Meeting, Salt Lake City, UT, March 2025.
- Jenewein EC, on behalf of the Pediatric Eye Disease Investigator Group. Normal versus abnormal retinal correspondence in children ages 6 to 8 with intermittent exotropia. Presented at the Association of Research in Vision and Ophthalmology Annual Meeting, Salt Lake City, UT, May 2025.
- Kerber KL, on behalf of the Pediatric Eye Disease Investigator Group. Evaluation of progression of astigmatism in myopic children. Presented at the Association of Research in Vision and Ophthalmology Annual Meeting, Salt Lake City, UT, May 2025.
- Repka MX, on behalf of the Pediatric Eye Disease Investigator Group. Does prior progression predict future change in axial length among children with myopia? Presented at the Association of Research in Vision and Ophthalmology Annual Meeting, Salt Lake City, UT, May 2025.
- Roberts TL, on behalf of the Pediatric Eye Disease Investigator Group. In-office visual acuity testing in children using a custom iPhone® application compared with standardized amblyopia treatment study protocols. Presented at the Association of Research in Vision and Ophthalmology Annual Meeting, Salt Lake City, UT, May 2025.
- Jenewein EC, on behalf of the Pediatric Eye Disease Investigator Group. A randomized clinical trial of full-time alternate patching therapy for intermittent exotropia in children. Presented at the American Academy of Optometry Annual Meeting, Boston, MA, October 2025.
- Manh VM, on behalf of the Pediatric Eye Disease Investigator Group. Testability and reliability of spot-checks contrast sensitivity in children with amblyopia aged 3 to 12 years. Presented at the American Academy of Optometry Annual Meeting, Boston, MA, October 2025.

## Diabetes Research

### Published and Accepted Manuscripts

- Akturk HK, Brown SA, **Beck RW**, et al. Registration and real-life studies on automated insulin delivery systems. *Diabetes Technol Ther* 2025; 27: S48-S59.
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- Raza Rizvi S, **Henderson RJ**, **Kanapka L**, Kahkoska A, Reid C, Desjardins D, Chaytor N, Weinstock RS, Rickels MR, Pratley RE, Kudva YC. Diabetes distress is associated with higher risk of hypoglycemia in older adults with type 1 diabetes in the AIDE trial. *Diabetes* 2025; 74: Supplement\_1. 605-P. doi:10.2337/db25-605-P.

- **Ruedy K, Calhoun P, Bailey R**, Polonsky WH, Hirsch IB, Hood KK, **Beck RW**. Patient-reported outcomes with use of inhaled Technosphere insulin (TI). *Diabetes* 2025; 74: Supplement\_1. 827-P. doi:10.2337/db25-827-P.
- Scott E, **Li Z, Calhoun P**, Kleinhappel T, Law G, **Sibayan J**, Norton E, Carlson A, Bergenstal R, **Beck R**, Murphy H, Durnwald C. Predicting adverse perinatal outcomes (APOs) using continuous glucose monitoring (CGM)-measured data from combined US and UK cohorts. *Diabetes Technol Ther* 2025; 27: S2. e87.
- Tillman J, **Beck RW**, Polonsky WH, **Calhoun P, Mouse TJ, Bailey R**, Nandan R. Observed glycemic and psychosocial benefits in the prospective Bigfoot Unity Real-World Study (BURST)—A twelve-month analysis. *Diabetes* 2025; 74: Supplement\_1. 1000-P. doi:10.2337/db25-1000-P.
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## Additional Eye Disease Studies

### Published and Accepted Manuscripts

- Jurkunas UV, Kaufman AR, Yin J, **Ayala A, Maguire M, Samarakoon L**, Johns LK, Parekh M, Li S, Gauthier A, Negre H, Shaw KL, Hernandez Rodriguez DE, Daley H, Dana R, Armant M, Ritz J. Cultivated autologous limbal epithelial cell (CALEC) transplantation for limbal stem cell deficiency: A phase I/II clinical trial of the first xenobiotic-free, serum-free, antibiotic-free manufacturing protocol developed in the US. *Nature Communications* 2025; 16: 1. 1607. doi:10.1038/s41467-025-56461-1.
- Lass JH, Benetz BA, Verdier DD, Szczotka-Flynn LB, **Bauza CE, Reed ZW**, Greiner MA, Mian SI, Patel SV, Pramanik S, Price FW, Jr., Soper MC, Terry MA, Titus MS, **Kollman C, Beck RW**, Price MO. Endothelial cell loss 1 year after successful DMEK in the Diabetes Endothelial Keratoplasty Study: A randomized clinical trial. *JAMA Ophthalmol* 2025; doi:10.1001/jamaophthalmol.2025.4261. PMID:41105099. PMC12534859.
- Panjwani M, **Beaulieu WT**, Kozak I, Holmes JM. VFQ-25 with and without Rasch scoring assessed using simulated data in trials comparing laser with anti-VEGF for diabetic retinopathy. *Trans Vis Sci Tech.* (accepted).

- Price FW, Jr., Szczotka-Flynn LB, Price MO, **Bauza CE**, **Reed ZW**, Arafah BM, Greiner MA, Johnson PJ, Keeler DB, Mian SI, Patel SV, Pramanik S, Soper MC, Terry MA, Titus MS, Verdier DD, **Kollman C**, **Beck RW**, Lass JH. Donor diabetes and 1-year Descemet membrane endothelial keratoplasty success rate: A randomized clinical trial. *JAMA Ophthalmol* 2025; doi:10.1001/jamaophthalmol.2025.4253. PMID:41105094. PMC12534858.
- Shah VN, **Kanapka LG**, **Beck RW**, Kovatchev B. Association between time-in-range and diabetic retinopathy: Learnings from DCCT to recent times. *Diabetes Technol Ther* 2025; 27: 765-767.
- Yavuz Saricay L, Kaufman AR, Johns LK, Yin J, **Samarakoon L**, **Ayala AR**, **Maguire M**, Parekh M, Hernandez Rodriguez DE, Daley H, Dana R, Armant M, Ritz J, Jurkunas UV. Central cornea changes on anterior segment OCT and in vivo confocal microscopy after autologous limbal epithelial cell transplantation. *Cornea* 2025; doi:10.1097/ico.0000000000003865.PMID:40152603.

### Presentations

- Diabetes Endothelial Keratoplasty Study primary results. Presented at the Cornea and Eye Banking Forum mini-symposium, Orlando, FL, October 2025.
- Diabetes Endothelial Keratoplasty Study primary results. Presented at the American Academy of Ophthalmology annual meeting (Cornea Subspecialty Day), Orlando, FL, October 2025.

## Cystic Fibrosis Studies

### Presentation

- Fonseca HR, **Reed ZW**, Alvarez JA, Freedman SD, Schwarzenberg SJ, **Sibayan J**, Stein AC. Baseline body composition of adults with preserved lung function in the STRONG-CF study. Presented at the North American Cystic Fibrosis Conference, October 2025.

## Additional Publications

### Published and Accepted Manuscripts

- **Glassman AR**. Anti-vascular endothelial growth factor options and questions for diabetic eye disease treatment. *JAMA Ophthalmol*. 2025;143(4):336–337. doi:10.1001/jamaophthalmol.2025.0007
- Padovani-Claudio DA, **Glassman AR**. Benefits and limitations of using population databases for eye research—more than meets the eye. *JAMA Ophthalmol*. 2025;143(11):944–945. doi:10.1001/jamaophthalmol.2025.3882.

## Appendix A: Staff Activities and Recognitions

### Ayala, Allison R.

- Journal Reviewer: International Journal of Molecular Sciences
- Panelist: FDA Sponsored Hybrid Meeting at Duke-Margolis Institute for Health Policy: Assessing Novel Efficacy Endpoints in Ophthalmologic Rare Disease Drug and Biologics Development

### Bauza, Colleen E.

- Grant Reviewer: Breakthrough T1D
- Journal Reviewer: Plos One; Journal of Stroke & Cerebrovascular Diseases

### Beaulieu, Wesley T.

- Journal Reviewer: Ophthalmology; JAMA Ophthalmology; Survey of Ophthalmology; American Journal of Ophthalmology; Ophthalmology Science; British Journal of Ophthalmology; Eye and Vision; Retina; Optometry and Vision Science; BMC Ophthalmology; Journal of the American Association of Pediatric Ophthalmology and Strabismus
- Methodologist: American Academy of Ophthalmology Ophthalmic Technology Assessment Committee Retina/Vitreous Panel
- Member: Data and Safety Monitoring Committee, Delaying the Onset of Nearsightedness Until Treatment (DONUT); funded by the National Eye Institute (NEI) of the National Institutes of Health (NIH)

### Beck, Roy W.

- Deputy Editor: JAMA Ophthalmology
- Senior Editor: Diabetes Technology and Therapeutics
- Journal Reviewer: Diabetes Technology and Therapeutics; JAMA; JAMA Ophthalmology; JAMA Network Open; Journal of Diabetes Science and Technology; Diabetes Care; Diabetes, Obesity, and Metabolism; Diabetes Research in Clinical Practice; Journal of Diabetes and Its Complications
- Grant Reviewer: Breakthrough T1D

### Calhoun, Peter M.

- Grant Reviewer: Breakthrough T1D
- Journal Reviewer: Canadian Journal of Diabetes; Diabetes Care; Diabetes Obesity and Metabolism; Diabetes Technology and Therapeutics; Diabetologia; Journal of Diabetes Science and Technology; Nature

**Chandler, Danielle L.**

- Peer Reviewer: American Journal of Ophthalmology

**Gal, Robin L.**

- Grant Reviewer: Breakthrough T1D
- Journal Reviewer: Diabetes Research and Clinical Practice
- Invited Presenter: Vivli Annual Conference
- Advisor and Contributing Member: INSPIRE T1D

**Glassman, Adam R.**

- Advisory Board Member: Cochrane Eye and Vision
- Editorial Board Member: JAMA Ophthalmology, Retina
- Grant Reviewer: Breakthrough T1D
- Journal Reviewer: JAMA Ophthalmology; Ophthalmology, Ophthalmology-Retina; Retina
- Member: Data and Safety Monitoring Committee; A Research Study Investigating Semaglutide in People With Early Alzheimer's Disease (EVOKE)

**Henderson, Robert J.**

- Grant Reviewer: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); National Institutes of Health Special Emphasis Panel, Breakthrough T1D (x2)
- Journal Reviewer: Optometry and Vision Science; Diabetes Technology & Therapeutics; National Catholic Bioethics Quarterly
- Member: Data and Safety Monitoring Board; Multicenter Clinical Trial to Evaluate the Safety and Efficacy of Ex Vivo Corneal Cross-linking of Donor Corneal Tissue Used for Vascularized High-Risk Keratoplasty (ExCrossV)

**Kollman, Craig**

- Grant Reviewer: Breakthrough T1D
- Member: DSMC, MELD-ATG Study

**Kraker, Raymond T.**

- Journal Reviewer: Journal of AAPOS; JAMA Ophthalmology; Optometry and Vision Science
- Grant Reviewer: Breakthrough T1D; UK Research and Innovation Medical Research Council (UKRI MRC)

**Liu, Danni**

- Journal Reviewer: JAMA Ophthalmology

**Lum, John W.**

- Board Member: Breakthrough T1D Tampa Bay Chapter
- Journal Reviewer: Diabetes Technology and Therapeutics; eClinicalMedicine; Endocrine Practice; Expert Opinion on Drug Delivery; Journal of Diabetes Science and Technology; Metabologia; Pediatric Diabetes

**Melia, Michele**

- Journal Reviewer: Investigative Ophthalmology and Vision Science (IOVS); JAMA Ophthalmology; Ophthalmology; Ophthalmology Science; Retina

**Sibayan, Judy**

- Grant Reviewer: Breakthrough T1D

**Stockdale, Cynthia R.**

- Journal Reviewer: JAMA Ophthalmology

**Tian, Wei**

- Journal Reviewer: American Journal of Ophthalmology

## Appendix B: Grants and Sub-Awards Active During 2025

### Cystic Fibrosis Foundation (CFF)

- **A Randomized Trial of the Insulin-only Bionic Pancreas in Cystic Fibrosis Related Diabetes (BP CFRD Main)**  
 Principal Investigator: Judy Sibayan, MPH  
 Funded through May 2026
- **Strength and Muscle Related Outcomes for Nutrition and Lung Function in CF (STRONG-CF)**  
 Principal Investigator: Judy Sibayan, MPH  
 Funded through May 2028
- **Studying the Presence and Development of CFRD and its Complications with Targeted Recruitment of Underrepresented Minority Groups (SPECTRUM-CF Planning)**  
 Principal Investigator: Judy Sibayan, MPH  
 Ended December 2025
- **Studying the Presence and Development of CFRD and its Complications with Thoughtful Recruitment of Multiethnic Minoritized (SPeCTRuM) groups (SPECTRUM – Main)**  
 Principal Investigator: Judy Sibayan, MPH  
 Funded through June 2029

### Food and Drug Administration (FDA)

- **Gyrate Atrophy Ocular and Systemic Study (GYROS)**  
 Joint funding with Foundation Fighting Blindness (FFB)  
 Principal Investigator: Allison Ayala, MS  
 Funded through December 2028

### Foundation Fighting Blindness (FFB)

- **Consortium Coordinating Center Core Efforts**  
 Principal Investigator: Allison Ayala, MS  
 Funded through June 2029
- **Gyrate Atrophy Ocular and Systemic Study (GYROS)**  
 Principal Investigator: Allison Ayala, MS  
 Funded through December 2028
- **Rate of Progression in EYS-Related Retinal Degeneration (Pro-EYS)**  
 Principal Investigator: Allison Ayala, MS  
 Funded through December 2026

- **Rate of Progression in PCDH15-Related Retinal Degeneration (RUSH1F)**  
Principal Investigator: Allison Ayala, MS  
Funded through December 2026
- **Rate of Progression in USH2A-Related Retinal Degeneration (RUSH2A)**  
Principal Investigator: Allison Ayala, MS  
Funded through December 2028
- **Universal Rare Gene Study: A Registry and Natural History Study of Retinal Dystrophies Associated with Rare Disease-Causing Genetic Variants (Uni-Rare)**  
Principal Investigator: Allison Ayala, MS  
Funded through December June 2028

### **Helmsley Charitable Trust (HCT)**

- **CGM for the Early Detection and Management of Dysglycemia in Pregnancy (IMAGINE)**  
Principal Investigator: Judy Sibayan, MPH  
Funded through September 2027
- **Educational Intervention to Support Diabetes Guidance for Exercise (EDGE)**  
Principal Investigator: Robin Gal, MSPH  
Funded through June 2026
- **Evaluation of the Relationship of Glucose Metrics via Continuous Glucose Monitoring with Diabetic Retinopathy (part of DRCR Protocol AF)**  
Joint funding with NIH, Breakthrough T1D, and F. Hoffman-La Roche, Ltd.  
Principal Investigator: Cynthia Stockdale, MSPH  
Funded through July 2029
- **Exercise in Diabetes Initiative: Large Adult Study (T1-DEXI3)**  
Joint funding with DexCom, Inc.  
Principal Investigator: Robin Gal, MSPH  
Ended January 2026
- **Leveraging New Ultra-rapid Insulins with AID for Exercise Management with T1D (Ultra-AID)**  
Principal Investigator: Robin Gal, MSPH  
Funded through April 2026
- **Pregnancy Data Repository to Assess Management of Type 1 Diabetes with Diabetes Technology (PRAM-T1D)**  
Principal Investigator: Robin Gal, MSPH  
Funded through December 2026

- **Virtual Diabetes Specialty Clinic: A Study Evaluating Remote Initiation of Continuous Glucose Monitoring (VDiSC)**  
Principal Investigator: Robin Gal, MSPH  
Funded through April 2026

## Breakthrough T1D

- **A Phase 2 Study Evaluating Short-Term Efficacy of Tonabersat (Xiflam) for Diabetic Macular Edema (DRCR Protocol AN)**  
Joint funding with NIH and InflammX Therapeutics, Inc.  
Principal Investigator: Adam Glassman, MS  
Ended January 2026
- **A Randomized Trial Evaluating Fenofibrate for Prevention of Diabetic Retinopathy Worsening (DRCR Protocol AF)**  
Joint funding with NIH, HCT, and F. Hoffman-La Roche, Ltd.  
Principal Investigator: Adam Glassman, MS  
Funded through January 2026
- **Breakthrough T1D Coordinating Center (Breakthrough T1D CC)**  
Principal Investigator: Judy Sibayan, MPH  
Funded through August 2027
- **Hybrid Closed Loop Therapy for Beta Cell Preservation in New Onset Type 1 Diabetes: Extension Study (CLVerEX)**  
Subaward through the University of Minnesota  
Principal Investigator: Alandra Verdejo, MPH  
Funded through January 2026
- **Mechanistic Etiologies Underlying the Impact of Verapamil to Preserve Beta Cell Function in Type 1 Diabetes (CLVer Mechanistic)**  
Subaward through the University of Minnesota  
Principal Investigator: Alandra Verdejo, MPH  
Funded through August 2026

## National Institutes of Health (NIH)

- **Accelerate Innovation of Diabetes Translation to Maximize Positive Impacts of Research on Population Health Through Activities and Core Services that Offer Specialized Expertise, Tools, Education, and Support (GCDTR)**  
Subaward through Emory University  
Principal Investigator: Peter Calhoun, PhD  
Funded through July 2026
- **Care partner-assisted ImplementatiOn of Patch Hybrid Closed Loop Insulin Delivery for Older Adults with T1D (COPILOT)**  
Principal Investigator: Robert Henderson, MS  
Funded through August 2028

- **Closed Loop and Education for hypoglycemia Awareness Restoration (CLEAR)**  
Subaward through Pennsylvania State University  
Principal Investigator: Robert Henderson, MS  
Funded through December 2027
- **Diabetes Endothelial Keratoplasty Study: Impact of Diabetes on Corneal Transplant Success and Endothelial Cell Loss (DEKS)**  
Principal Investigator: Robin Gal, MSPH  
Funded through April 2026
- **DRCR Retina Network (DRCR)**  
Principal Investigator: Adam Glassman, MS  
Funded through December 2028
- **Pediatric Eye Disease Investigator Group (PEDIG)**  
Principal Investigator: Raymond Kraker, MSPH  
Funded through December 2028

### National Institute for Health and Care Research

- **PROTECT Pregnancy Outcomes Using Continuous Glucose Monitoring TEChnology in Pregnant Women with Type 2 Diabetes: A Multicentre Randomised Controlled Trial of the Clinical and Cost-Effectiveness of Using Continuous Glucose Monitoring in Pregnant Women with Type 2 Diabetes (PROTECT)**  
Subaward through University of East Anglia  
Principal Investigator: Robin Gal, MSPH  
Funded through April 2027

### Other Funding Sources

- **A 17-Week Randomized Trial and a 13-Week Extension, Evaluating the Efficacy and Safety of Inhaled Insulin (Afrezza®) Combined with Insulin Degludec Versus Usual Care in Adults with Type 1 Diabetes (INHALE-3)**  
Funding from MannKind Corporation  
Principal Investigator: Katrina Ruedy
- **A 26-week Primary Treatment Phase, with 26-week Extension, Open-label, Randomized Clinical Trial Evaluating the Efficacy and Safety of Afrezza® Versus Rapid-acting Insulin Analog Injections, Both in Combination with a Basal Insulin, in Pediatric Subjects with Type 1 or Type 2 Diabetes Mellitus (INHALE-1)**  
Funding from MannKind Corporation  
Principal Investigator: Robin Gal, MSPH

- **A Pilot Study Evaluating Short-Term Efficacy of Xiflam for Diabetic Macular Edema (DRCR Protocol AN)**  
 Funding from InflammX Therapeutics, Inc.  
 Principal Investigator: Claire Calhoun
- **A Randomized Clinical Trial Evaluating Intravitreal Faricimab (6.0 mg) Injections or Fluocinolone Acetonide (0.19 mg) Intravitreal Implants versus Observation for Prevention of Visual Acuity Loss due to Radiation Retinopathy (DRCR Protocol AL)**  
 Funding from Alimera Sciences, Inc. and Genentech, Inc.  
 Principal Investigator: Carrie Preston
- **A Randomized Placebo-controlled Trial of Spectacles with Highly Aspherical Lenslets or 0.05% Atropine to Slow Progression of Myopia in Children (PEDIG Protocol MTS2)**  
 Funding from Essilor International  
 Principal Investigator: Raymond Kraker, MSPH
- **A Randomized Trial Evaluating Fenofibrate for Prevention of Diabetic Retinopathy Worsening (DRCR Protocol AF)**  
 Joint funding with Lowy Medical Research Institute, Ltd.; F. Hoffman-La Roche, Ltd.; Helmsley Charitable Trust; Breakthrough T1D; and NIH  
 Principal Investigator: Cynthia Stockdale, MSPH
- **A Randomized Trial Evaluating the Efficacy and Safety of Control-IQ Technology in Adults with Type 2 Diabetes Using Basal-Bolus Insulin Therapy (2IQP)**  
 Funding from Tandem Diabetes Care, Inc.  
 Principal Investigator: John Lum, MS
- **A Randomized Trial to Evaluate Treatment of Maternal Dysglycemia Diagnosed with Continuous Glucose Monitoring Between 10 to 16 Weeks of Gestation to Decrease the Risk of Gestational Diabetes Mellitus and Adverse Pregnancy Outcomes (IMAGINE)**  
 Funding from Abbott Diabetes Care Sales Corporation and DexCom, Inc.  
 Principal Investigator: Judy Sibayan, MPH
- **A Single-arm Trial with an Innovative Automated Insulin Delivery System for Type 2 Diabetes (twiist)**  
 Funding from Sequel Med Tech, LLC and DEKA Research & Development Corp.  
 Principal Investigator: Thomas Mouse
- **Bigfoot Unity Real World Study (BURST)**  
 Funding from Bigfoot Biomedical, Inc.  
 Principal Investigator: Thomas Mouse

- **Breaking Health Care Disparities in Access to Advanced Diabetes Technologies in Children with Type 1 Diabetes**  
 Funding from The Nemours Foundation  
 Principal Investigators (JCHR): Adam Glassman, Roy Beck, and Craig Kollman
- **CONtiNuous glucosE monitoring (CGM) in people wiTh type 2 diabetes not on insulin: The CONNECT Study (CONNECT)**  
 Funding from DexCom, Inc. and DexCom Asia Pacific Operations PTE. LTD.  
 Principal Investigator: Katrina Ruedy
- **Home OCT-Guided Treatment versus Treat and Extend for the Management of Neovascular AMD (DRCR Protocol AO)**  
 Funding from Genentech, Inc.  
 Principal Investigator: Claire Calhoun
- **Open, Single Arm, Prospective, Multicenter Study of an Investigational Extended Wear Insulin Infusion Set During Home Use in People with Type 1 Diabetes (StediSet)**  
 Funding from Tandem Diabetes Care, Inc.  
 Principal Investigator: John Lum, MS
- **Safety and Efficacy of the Omnipod 5™ Automated Insulin Delivery System in Adults with Type 2 Diabetes (SECURE-T2D)**  
 Funding from Insulet Corporation  
 Principal Investigator: Katrina Ruedy
- **Safety and Efficacy of the Omnipod® 5 SA2.0 System Compared to the Omnipod 5 System in Individuals with Type 1 Diabetes (STRIVE)**  
 Funding from Insulet Corporation  
 Principal Investigator: Katrina Ruedy
- **Safety Evaluation of MODI, an Insulin Titration Algorithm, in Adults with Type 1 and Type 2 Diabetes. (MODI)**  
 Funding from Abbott Diabetes Care Inc. and DreaMed Diabetes Ltd.  
 Principal Investigator: John Lum, MS
- **Technosphere Insulin (Afrezza) In Combination with Basal Insulin for Youth with Newly Diagnosed Type 1 Diabetes (MKC-TI-196) (INHALE-1<sup>st</sup>)**  
 Funding from MannKind Corporation  
 Principal Investigator: Thomas Mouse

- **The Safety and Efficacy of Rapid Acting Inhaled Technosphere Insulin (Afrezza) Compared with Subcutaneous Insulin to Achieve Pregnancy-Specific Postprandial Targets among Patients with Gestational Diabetes (INHALE-GDM)**  
Funding from MannKind Corporation  
Principal Investigator: Katrina Ruedy
- **Time In Glucose Hospital Target (TIGHT RCT and TIGHT ICU)**  
Funding from DexCom, Inc.  
Principal Investigator: Judy Sibayan, MPH

## Appendix C: Summary Financial Information

The fiscal year 2025 summary financial information for the Jaeb Center for Health Research Foundation, Inc., and its affiliate, the Jaeb Center Research Trust, Inc., is presented in the following table.

**Note:**

As of the publication date, the audit for fiscal year 2025 was incomplete. Accordingly, the numbers reflected here are unaudited. The final audited numbers may vary slightly.

<b>Jaeb Center for Health Research and Affiliate Summary Financial Information Fiscal Year 2025</b>			
<b>Assets</b>	\$67,144,254	<b>Revenues</b>	\$61,335,833
<b>Liabilities</b>	\$31,195,094	<b>Expenses</b>	\$56,971,397
<b>Net Assets</b>	\$35,949,160	<b>Change in Net Assets</b>	\$4,364,436

The combined assets of \$67,144,254 increased year over year by \$10,222,272 or 18.0 percent. This is primarily the result of an increase in receivables, market gains in investment accounts, and capitalized investments in new software systems for the entire organization that will depreciate in future years. The combined liabilities of \$31,195,094 increased year over year by \$5,857,836 or 23.1 percent, most of which is related to an increase in payables and unearned revenue resulting from milestone payments received for industry projects for which the research has not yet been completed. Net assets of \$35,949,160 increased year over year by \$4,364,436 or 13.8 percent.

Combined revenues of \$61,335,833 increased year over year by \$7,909,570 or 14.8 percent. The bulk of this increase results from an increase in non-government private grants and, to a more limited extent, non-government industry-related clinical trial revenue. Combined expenses of \$56,971,397 increased year over year by \$6,505,127 or 12.9 percent. Most of this stems from increases in personnel costs as the organization has increased both direct and indirect staff costs to support the growing organization, payments to clinical sites for the conduct of research activities, and information technology expenses to support the growing organization.