



**JAEB CENTER FOR HEALTH RESEARCH
2024 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) is now in its 32nd year of improving public health. This report provides an overview of our research achievements over the past year.

In 2024, JCHR maintained its reputation for producing high-quality, data-driven results, contributing to advancements in diabetes, eye disease, and cystic fibrosis research. JCHR's involvement in diabetes studies continues to expand as it solidified its reputation as the premiere coordinating center worldwide for diabetes device studies.

JCHR was actively engaged in 50 clinical studies, which culminated in 51 scientific publications and 50 presentations at prominent national and international conferences. Our mission to expand scientific knowledge and improve health outcomes continues to drive the design and execution of world-class research.

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

- **Diabetes Research:** Ongoing projects evaluated various diabetes management technologies, including artificial pancreas systems, insulin pumps, continuous glucose monitors (CGMs), and therapies such as inhaled insulin. JCHR's research spans type 1, type 2, gestational, and cystic fibrosis-related diabetes.
- **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 coordinated two studies on corneal transplant techniques.

- **Cystic Fibrosis Research:** JCHR's growing research portfolio included projects addressing cystic fibrosis-related diabetes and other complications. 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.

In terms of funding, JCHR secured grants from leading organizations, including the National Institutes of Health (8), Helmsley Charitable Trust (10), Breakthrough T1D (6), Foundation Fighting Blindness (6), Cystic Fibrosis Foundation (5), Food and Drug Administration (1), and National Institute for Health and Care Research (1). Collaborations with 14 additional partners spanned 21 studies, including 9 investigator-initiated studies, underscoring JCHR's role as a trusted research partner.

Several studies are funded by multiple sources. For example, one clinical trial evaluating fenofibrate for diabetic retinopathy is a large collaboration with funds provided by the National Institutes of Health (National Eye Institute and National Institute of Diabetes and Digestive and Kidney Disease), Breakthrough T1D, Helmsley Charitable Trust, and Roche. JCHR also self-funded one study and numerous statistical analysis projects using datasets from previously completed studies. Among approximately 2,845 entities receiving NIH funding in 2024, JCHR ranks in the top 9 percent. Out of approximately 65,000 NIH grants awarded in 2024, JCHR had the 178th- (top 0.3 percent) and 312th- (top 0.47 percent) largest grants (source: Blue Ridge Institute for Medical Research, 2024).

JCHR's studies in 2024 led to several high-impact findings with clinical and regulatory implications. Notable results include:

Diabetes Studies:

1. SECURE-T2D Trial Results:

- This study demonstrated that the Omnipod® 5 Automated Insulin Delivery System was safe and effective for adults with type 2 diabetes, helping to optimize glucose control. The results of the trial lead to FDA approval of Omnipod® 5 for patients with type 2 diabetes.

2. Evaluation of Ultra-Rapid Lispro Insulin with Control-IQ Technology:

- A multicenter study evaluated the use of ultra-rapid lispro (URLi) insulin in combination with Control-IQ technology across adults, adolescents, and children with type 1 diabetes. The results showed that URLi insulin improved postprandial glucose control and enhanced overall time in range, highlighting its effectiveness as part of an advanced automated insulin delivery system. This study led to Tandem Diabetes Care, Inc., obtaining European Union (EU) clearance for the t:slim X2 insulin pump with Control-IQ automated insulin delivery (AID) technology with the use of Eli Lilly and Company's Lyumjev® (insulin lispro-aabc injection) ultra-rapid-acting insulin.

3. Impact of CGM on Pregnancy Outcomes:

- The study demonstrated that continuous glucose monitoring (CGM) was comparable to oral glucose tolerance test for diagnosing gestational diabetes and useful in predicting adverse perinatal outcomes.

4. Exercise and Glucose Control in Type 1 Diabetes (T1DEXI Study):

- This research showed that strategic exercise could reduce hyperglycemia risk without causing hypoglycemia. The study also revealed important sex differences in diabetes self-management strategies.

5. Automated Insulin Delivery (AID) for Older Adults:

- A randomized trial found that older adults with Type 1 diabetes significantly benefited from AID systems, experiencing improved glycemic control and enhanced quality of life.

6. Inhaled Insulin Plus Basal Insulin vs. Usual Care:

- A randomized trial compared the effectiveness of inhaled insulin combined with basal insulin to standard care in adults with type 1 diabetes. The study found that the combination of inhaled and basal insulin was non-inferior to standard care consisting predominately of either an automated insulin delivery system or multiple daily insulin injections. These findings highlight the potential for inhaled insulin as a viable alternative to traditional rapid-acting insulin therapy and to enhance diabetes management strategies.

Eye Disease Studies:**1. Advanced Retinal Imaging for Diabetic Retinopathy:**

- Research from the DRCR Retina Network highlighted that lesion types and their distribution on ultrawide field imaging are associated with the progression of diabetic retinopathy, aiding risk assessment for patients.

2. Retinal Degeneration Progression:

- The RUSH2A study offered key findings on the progression rates of USH2A-related retinal degeneration, which will guide future clinical trials in rare retinal diseases.

3. Corneal Transplant Research:

- A study on cultivated autologous limbal epithelial cell (CALEC) transplantation revealed improved central corneal structure and function in patients with limbal stem cell deficiency one year after treatment.

Executive Director Adam Glassman led a growing team of 170 employees, while Founder and Medical Director Dr. Roy W. Beck remained active in both research and governance roles. As of year-end, more than half of our employees have been with JCHR for five years or longer, reflecting the organization's strong retention in a home-centric work environment. With certainty, 2025 will be another busy and productive year for JCHR.

Studies Active During 2024

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 2024; 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 (DRCR Protocol AN)
- 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)
- 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)
- 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 of Overminus Spectacle Therapy for Intermittent Exotropia (IXT5)*
- A Randomized Clinical Trial to Evaluate Sequential versus Simultaneous Spectacles plus Patching (ATS22)
- A Randomized Trial of Bilateral Lateral Rectus Recession versus Unilateral Lateral Rectus Recession with Medial Rectus Resection for Intermittent Exotropia (IXT1Ext)*
- A Randomized Trial to Evaluate Low-Dose Atropine as Treatment for Myopia (MTS1)*
- Bevacizumab Treatment for Type 1 Retinopathy of Prematurity (ROP4)
- Evaluation of Accommodative Behavior in Children With and Without Amblyopia (ATS21)*
- Home Visual Acuity Testing (X06)*
- 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 (INHALE1)
- 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 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)
- 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)
- An Observational Study of Adults with Type 2 Diabetes Using the Community-Derived Open-Source Automated Insulin Delivery (OS-AID) Loop System: Loop T2D Observational Study (T2D Loop)
- An Observational Study to Assess CGM Accuracy in the ICU in People Being Treated with Insulin (TIGHT-ICU)
- Breaking Health Care Disparities in Access to Advanced Diabetes Technologies in Children with Type 1 Diabetes
- Breakthrough T1D CGM in Prevention*
- CONTiNuous glucosE monitoring (CGM) in people wiTh type 2 diabetes not on insulin: The CONNECT Study (CONNECT)
- Control-IQ Technology in Individuals with Type 2 Diabetes (2IQ)*
- Evaluating the Efficacy and Safety of Inhaled Insulin (Afrezza®) Combined with Insulin Degludec Versus Usual Care in Adults with Type 1 Diabetes (INHALE3)
- 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 (SteadySet)
- 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 Evaluation of an Advanced Hybrid Closed Loop System Using Lyumjev with the Tandem t:slim X2 with Control-IQ in Adults, Adolescents and Children with Type 1 Diabetes (TL1 Lyumjev)*
- Study of Preconception Food Security, Glycemia, and Nutrition CGM Data Management and Analysis (SPOON)
- 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 Pediatric Artificial Pancreas Trial: A Randomized Controlled Comparison of the Control-IQ Technology Versus Standard of Care in Young Children in Type 1 Diabetes (PEDAP)*
- Time In Glucose Hospital Target (TIGHT) – A Randomized Clinical Trial to Evaluate the Use of CGM to Achieve a Mean Glucose Target of 90 to 130 mg/dL Without Hypoglycemia in Hospitalized Adults with Type 2 Diabetes (TIGHT RCT)
- 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)*
- Virtual Diabetes Specialty Clinic: A Study Evaluating Remote Initiation of Continuous Glucose Monitoring (VDiSC)*

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

- Strength and Muscle Related Outcomes for Nutrition and Lung Functions in CF (STRONG-CF)

Additional Studies

- Glucose Levels Across Maternity (GLAM)*

Manuscripts and Presentations

Note:

JCHR employees appear in boldface type.

DRCR Retina Network

Published and Accepted Manuscripts

- Blinder KJ, **Calhoun C**, **Maguire MG**, **Glassman AR**, Mein CE, Baskin DE, Vieyra G, Jampol LM, Chica MA, Sun JK, Martin DF; DRCR Retina Network. Home OCT imaging for newly diagnosed neovascular age-related macular degeneration: a feasibility study. *Ophthalmol Retina*. 2024 Apr;8(4):376-387.
- 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*. 2024 Aug 30:S2468-6530(24)00402-0. doi: 10.1016/j.oret.2024.08.015. Epub ahead of print. PMID: 39216727.
- Jhaveri CD, **Liu D**, **Maguire MG**, **Glassman AR**, Grigorian RA, Jampol LM, Kingsley RM, MacCumber MW, Martin DF, Maturi RK, Velez G, Sun JK, DRCR Retina Network. Risk factors for meeting criteria for switching from bevacizumab to aflibercept when treating eyes with diabetic macular edema and Visual Acuity <20/40. *Ophthalmology*. 2024 Aug;131(8):967-974. doi: 10.1016/j.ophtha.2024.01.037. Epub 2024 Feb 8.
- Lee B, **Josic K**, Nittala MG, Velaga SB, Karamat A, Srinivas S, Corvi F, Singh G, Sadda S, Sun JK, Ip M, for the DRCR Retina Network. Long-term effects of intravitreal ranibizumab compared with panretinal photocoagulation on optical coherence tomography measured choroidal thickness and vascularity. *Transl Vis Sci Technol*. 2024 Jul 1;13(7):19. doi: 10.1167/tvst.13.7.19. (Published).
- 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*. 2024 Sep 12. doi: 10.1097/IAE.0000000000004263. Epub ahead of print. PMID: 39284035.

Presentations

- Martin D. Protocol AK home OCT monitoring system: feasibility study. Presented at the 47th Annual Macula Society Meeting, Palm Springs, CA, February 2024.

- Sun JK. Assessment of baseline UWF-A quantitative leakage parameters with clinical parameters in DR: Protocol AA. Presented at the 47th Annual Macula Society Meeting, Palm Springs, CA, February 2024.
- Ehlers J. Potential for refining DR severity comparative analysis of ultrawide field color and ultrawide field fluorescein angiography. Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Seattle, WA, May 2024.
- Lou Y. Genome-wide association study (GWAS) of anti-VEGF treatment response in diabetic macular edema identifies genetic associations with retina central subfield thickness and visual acuity improvement. Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Seattle, WA, May 2024.
- Silva P. Diabetic retinopathy lesion types and location on ultrawide field imaging and the risk of disease worsening over time. Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Seattle, WA, May 2024.
- **Calhoun C.** Singapore Eye Research Institute. Presented at the 42nd Annual American Society of Retina Specialists Scientific Meeting, Stockholm, Sweden, July 2024.
- Martin D. Effect of patient age on response to anti-VEGF agents for treating diabetic macular edema. Presented at the 42nd Annual American Society of Retina Specialists Scientific Meeting, Stockholm, Sweden, July 2024.
- Silva P. Diabetic retinopathy lesion types and distribution on ultrawide field imaging and the risk of disease worsening over time. Presented at the 42nd Annual American Society of Retina Specialists Scientific Meeting, Stockholm, Sweden, July 2024.
- Salehi-H. Partnering with a diagnostic laboratory to screen and enrich patient recruitment for clinical studies of diabetic retinal disease: a feasibility study. Presented at The Retina Society 57th Annual Scientific Meeting, Lisbon, Portugal, September 2024.
- Silva P. Diabetic retinopathy lesion types and distribution on ultrawide field imaging and the risk of disease worsening over time. Presented at The Retina Society 57th Annual Scientific Meeting, Lisbon, Portugal, September 2024.
- Jhaveri C, **Stockdale C**, Sun JK, Martin DF, **Melia M**, Jampol L. Clinical trial methodology and interpretation with examples from the DRCR Retina Network. Presented at the American Academy of Ophthalmology 2024 Annual Meeting, Chicago, IL, October 2024.

Foundation Fighting Blindness Clinical Consortium

Published and Accepted Manuscripts

- Birch DG, **Cheng P**, **Maguire MG**, Duncan JL, **Ayala AR**, Cheetham JK, **Doucet NR**, Durham TA, Fahim AT, Ferris FL, Huckfeldt RM, **Melia M**, Michaelides M, Pennesi ME, Sahel JA, Stingl K, Vincent A, Weng CY for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Visual acuity, full-field stimulus thresholds, and electroretinography for 4 years in the rate of progression of USH2A-related retinal degeneration (RUSH2A) study. *Ophthalmology Science*. 2025 March-April; 5:2(10). <https://doi.org/10.1016/j.xops.2024.100648>.
- Heon E, **Melia M**, **Bocchino LE**, **Samarakoon L**, Duncan JL, **Ayala AR**, Audo I, Bradley C, Cheetham JK, Dagnelie G, Durham TA, Hoyng CB, Jain N, Jayasundera KT, Pennesi ME, Weng CY for the Foundation Fighting Blindness Consortium Investigator Group. Functional vision in patients with bi-allelic USH2A variants. *Am J Ophthalmol*. 2024; 260: 200-211. PMID: 38135239.
- **Maguire MG**, Birch DG, Duncan JL, **Ayala AR**, Ayton LN, Cheetham JK, **Cheng P**, Durham TA, Ferris FL, Hoyng CB, Huckfeldt RM, Jaffe GJ, Kay C, Lad EM, Leroy BP, **Liang W**, **McDaniel LS**, **Melia M**, Michaelides M, Pennesi ME, Sahel JA, Samarakoon L for the REDI Working Group and the Foundation Fighting Blindness Clinical Consortium Investigator Group. Endpoints and design for clinical trials in USH2A-related retinal degeneration: results and recommendations from the RUSH2A natural history study. *Transl. Vis. Sci. Technol*. 2024 Oct 1;13(10):15. doi: 10.1167/tvst.13.10.15. PMID: 39382872; PMCID: PMC11469320.
- Parekh B, Duncan JL, **Samarakoon L**, **Melia M**, 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, Peck-Dimit N, Stingl K, Weng CY, Zmejkoski AZ, Jayasundera KT for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Self-reported functional vision in USH2A-associated retinal degeneration as measured by the Michigan Retinal Degeneration Questionnaire. *Invest Ophthalmol Vis Sci*. 2024 Jun 3;65(6):5. doi: 10.1167/iovs.65.6.5. PMID: 38833260; PMCID: PMC11156206.

Presentations

- Huckfeldt R, for the Foundation Fighting Blindness Consortium Investigator Group. Trial endpoints for USH2A-related retinal degeneration: results and recommendations of the RUSH2A natural history study and REDI working group initiative. Presented at the 47th Annual Macula Society Meeting, Palm Springs, CA, February 2024.

- Sahel JA, for the Foundation Fighting Blindness Consortium Investigator Group. Trial endpoints for USH2A-related retinal degeneration: results and recommendations of the RUSH2A natural history study and REDI working group initiative. Presented at the Young Hadassah Eye and Vision Innovation Forum, Hadassah Medical Center, Jerusalem, Israel, March 2024.
- Singh M, for the Foundation Fighting Blindness Consortium Investigator Group. Gyrate atrophy ocular and systemic study (GYROS). Presented at the Patient Foundation; Mexico City, Mexico, April 2024.
- Valle D, for the Foundation Fighting Blindness Consortium Investigator Group. Gyrate atrophy of the choroid and retina: past, present, future. Presented at the Mexican Symposium on Gyrate Atrophy, Mexico City, Mexico, April 2024.
- **Ayala AR**, Huckfeldt RM, Duncan JL, Vincent A, Lad EM, Birch DG, Jayasundera KT, **Maguire MG** for the Foundation Fighting Blindness Clinical Consortium Investigator Group. RUSH2A natural history study: 4-year progression data and implications for future trial design. Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Seattle, WA, May 2024.
- Miller A, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Static perimetry-OCT topographical overlay findings in the RUSH2A study. Presented at Advances in Ophthalmic Technology, Association for Research in Vision and Ophthalmology Annual Meeting, Seattle, WA, May 2024.
- **Ayala AR**, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Full-field sensitivity testing as an outcome measure—functional transition points (FTPs). Presented at the Retina International World Congress and ERN-EYE, Dublin, Ireland, June 2024.
- Birch D, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Full-field sensitivity testing as an outcome measure. Presented at the Retina International World Congress and ERN-EYE, Dublin, Ireland, June 2024.
- Huckfeldt R, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. REDI working group: RUSH2A key findings. Presented at the Retina International World Congress and ERN-EYE, Dublin, Ireland, June 2024.
- Birch D, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. REDI working group: FST data review. Presented at the Ocular Disease Forum 2, Washington, DC, September 2024.

- Duncan J, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. REDI working group: RUSH2A endpoints key findings. Presented at the Ocular Disease Forum 2, Washington, DC, September 2024.
- Huckfeldt R, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Leveraging multicenter natural history data for endpoint development in inherited retinal disorders. Presented at the Mary Tyler Moore Vision Initiative Symposium, Ann Arbor, MI, November 2024.
- Huckfeldt R, for the Foundation Fighting Blindness Clinical Consortium Investigator Group. Leveraging multicenter natural history data for endpoint development in inherited retinal disorders. Presented at the Association for Research in Vision and Ophthalmology Frontiers in Ocular Gene Therapy Research Conference (virtual), November 2024.

Pediatric Eye Disease Investigator Group

Published and Accepted Manuscripts

- de Alba Campomanes AG, Repka MX, Hatt SR, **Sutherland DS**, Leske DA, Morrison DG, Fallaha N, **Melia BM**, **Kraker RT**, Cotter SA, Holmes JM; on behalf of PEDIG. Myopic shift over five years following pediatric lensectomy with primary intraocular lens implantation. *Ophthalmology*. Published online September 6, 2024. doi:10.1016/j.ophtha.2024.08.036. [Online ahead of print]
- Donahue SP, **Chandler DL**, **Wu R**, Marsh JD, Law C, Areaux RG Jr, Ghasia FF, **Li Z**, **Kraker RT**, Cotter SA, Holmes JM; on behalf of PEDIG. Eight-year outcomes of bilateral lateral rectus recessions versus unilateral recess-resect in childhood basic-type intermittent exotropia. *Ophthalmology* 2024;131(1):95-106.
- Haider KM, Repka MX, **Sutherland DR**, Hatt SR, Fallaha N, **Kraker RT**, **Melia BM**, Cotter SA, Holmes JM; on behalf of PEDIG. Outcomes and complications 5 years following surgery for pediatric cataract associated with persistent fetal vasculature. *Am J Ophthalmol*. 2024;260:30-36.
- Miller AM, Holmes JM, **Wu R**, **Kraker RT**, Crouch ER, Lee KA, Del Monte MA, Marsh JD, Kraus CL, Wallace DK, Colburn JD, Kemp PS, Cotter SA; on behalf of PEDIG. Doses of medial rectus muscle recessions for divergence insufficiency-type esotropia. *J AAPOS* 2024;28(3):103905.
- Wang S, Repka MX, **Sutherland DR**, Hatt SR, Traboulsi EI, Lambert SR, **Melia BM**, **Kraker RT**, Holmes JM, Cotter SA; on behalf of PEDIG. Complications, visual acuity, and refractive error three years after secondary intraocular lens implantation for pediatric aphakia. *Ophthalmology*. 2024;131(10):1196-1206.

- Weise KK, Repka MX, **Zhu Y**, Manny RE, Raghuram A, **Chandler DL**, Summers AI, Lee KA, Kehler LAF, Pang Y, Allen MS, Anderson HA, Erzurum SA, Golden RP, Koutnik CA, Kuo AF, Lenhart PD, Mokka PL, Petersen DB, Ticho BH, Wiecek EK, Yin H, **Beaulieu WT**, **Kraker RT**, Holmes JM, Cotter SA; on behalf of PEDIG. Baseline factors associated with myopia progression and axial elongation over 30 months in children 5 to 12 years of age. 2024. *Optom Vis Sci.* 2024;101(10):619-626.
- Writing Committee for the Pediatric Eye Disease Investigator Group, Chen AM, Erzurum SA, **Chandler DL**, Hercinovic A, **Wu R**, Vricella M, Waters AL, Ticho BH, Erickson JW, Han S, McDowell PS, **Li Z**, **Kraker RT**, Holmes JM, Cotter SA. Refractive error change and overminus lens therapy for childhood intermittent exotropia. *JAMA Ophthalmol.* 2024;142(5):417-428.

Presentations

- Crouch, ER; on behalf of the Pediatric Eye Disease Investigator Group. Association of initial post-op alignment with long-term outcome when performing surgery for intermittent exotropia. Presented at the American Association for Pediatric Ophthalmology and Strabismus Annual Meeting, Austin, TX, April 2024 (paper presentation).
- De Alba Campomanes, AG; on behalf of the Pediatric Eye Disease Investigator Group. Ophthalmic outcomes five years after cataract surgery among children with Down syndrome. Presented at the American Association for Pediatric Ophthalmology and Strabismus Annual Meeting, Austin, TX, April 2024 (poster presentation).
- Raghuram, A; on behalf of the Pediatric Eye Disease Investigator Group. Validity of accommodative amplitude and accuracy by Nott dynamic retinoscopy in children with amblyopia. Presented at the American Association for Pediatric Ophthalmology and Strabismus Annual Meeting, Austin, TX, April 2024 (poster presentation).
- Roberts, TL; on behalf of the Pediatric Eye Disease Investigator Group. Accommodation in children with and without amblyopia. Presented at the American Association for Pediatric Ophthalmology and Strabismus Annual Meeting, Austin, TX, April 2024 (poster presentation).
- Erzurum, SA; on behalf of the Pediatric Eye Disease Investigator Group. Treatments for chalazia in children 4 to <18 years of age. Presented at the American Academy of Ophthalmology Annual Meeting, Chicago, IL, October 2024 (poster presentation).

- Roberts, TL; on behalf of the Pediatric Eye Disease Investigator Group. Associations between accommodative behavior, age, and visual acuity in children with and without amblyopia. Presented at the American Academy of Optometry Annual Meeting, Indianapolis, IN, November 2024 (poster presentation).
- Waters, AL; 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 Academy of Optometry Annual Meeting, Indianapolis, IN, November 2024 (poster presentation).

Diabetes Studies

Published and Accepted Manuscripts

- **Bailey R, Calhoun P**, Garg SK. Weight gain and glycemic control in adults with type 1 diabetes in the T1D Exchange registry. *Diabetes Technol Ther* 2024; 26: 3. 156-160. doi:10.1089/dia.2023.0389.PMID:38444314.
- **Bauza C, Kanapka LG**, Greene E, Lal RA, Arbiter B, **Beck RW**. Use of the community-derived open-source automated insulin delivery loop system in type 2 diabetes. *Diabetes Technol Ther* 2024; doi:10.1089/dia.2023.0569. PMID:38386434.
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Presentations

- **Bergford S**, Riddell M, Gal RL, Sherr J, Patton S, Clements M, **Calhoun P**. Predicting hypoglycemia and hyperglycemia during and after exercise for adolescents in the Type 1 Diabetes EXercise Pediatric Study (T1DEXIP). Presented at the 17th International Conference on Advanced Technologies & Treatments for Diabetes, Florence, Italy, March 2024.
- **Calhoun P**, **Bailey R**, Garg S. Weight gain and glycemic control in adults with type 1 diabetes in the T1D Exchange registry. Presented at the 17th International Conference on Advanced Technologies & Treatments for Diabetes, Florence, Italy, March 2024.
- **Calhoun P**, **Raghinaru D**, Bergenstal R, **Beck R**. A comparison of CGM-measured time-in-range 70-180 mg/dL versus time-in-tight-range 70-140 mg/dL. Presented at the 17th International Conference on Advanced Technologies & Treatments for Diabetes, Florence, Italy, March 2024.
- Hirsch I. Post-prandial glucose following a bolus with inhaled insulin versus usual care. Presented at the 17th International Conference on Advanced Technologies & Treatments for Diabetes, Florence, Italy, March 2024.
- Levy CL, **Bailey R**, Laffel L, Forlenza G, DiMeglio L, Lal R, Brown SA, Aleppo G, Bhargava A, Shah VN, Clements M, Kipnes M, Bruggeman B, Daniels M, Rodriguez H, **Beck R**, Sasson-Katchalski R, Pinsker JE, Pollom R. High satisfaction with Control-IQ 1.5 and Iyumjev insulin in children, adolescents and adults with type 1 diabetes. Presented at the 17th International Conference on Advanced Technologies & Treatments for Diabetes, Florence, Italy, March 2024.
- Riddell M, Gal RL, Sherr J. Lessons learned from the ongoing type 1 diabetes research initiative. Presented at the 17th International Conference on Advanced Technologies & Treatments for Diabetes, Florence, Italy, March 2024.
- Bilal A, Casu A, Yi F, Mucinski J, Mercouffer G, Kelley D, Pratley RE. A randomized study of a GPR119 agonist on glucagon counter-regulation during hypoglycemia in type 1 diabetes mellitus (T1D). Presented at the 84th Scientific Sessions of the American Diabetes Association, Orlando, FL, June 2024.
- **Calhoun P**, **Spanbauer C**, Steck A, Frohnert B, Herman M, Keymeulen B, Veijola R, Toppari J, Desouter A, Gorus F, Atkinson M, Wilson DM, Pietropaolo S, **Beck R**. CGM metrics from five studies identify participants at high risk of imminent type 1 diabetes (T1D) development. Presented at the 84th Scientific Sessions of the American Diabetes Association, Orlando, FL, June 2024.

- Carlson AL, **Li Z**, **Beck R**, Durnwald C, Norton E, Bergenstal RM, Johnson ML, Dunnigan SM, Banfield M, Krumwiede KJ, **Sibayan J**, **Calhoun P**. Postprandial glycemic patterns throughout uncomplicated pregnancies. Presented at the 84th Scientific Sessions of the American Diabetes Association, Orlando, FL, June 2024.
- Hirsch I. A randomized trial comparing inhaled insulin plus insulin degludec versus usual care insulin delivery in adults with type 1 diabetes (T1D). Presented at the 84th Scientific Sessions of the American Diabetes Association, Orlando, FL, June 2024.
- Jacobs P, **Marak MC**, **Calhoun P**, **Gal RL**, Castle J, Riddell MC. Real-world evaluation of exercise consensus guidelines in adults with type 1 diabetes: new finding from the T1DEXI study. Presented at the 84th Scientific Sessions of the American Diabetes Association, Orlando, FL, June 2024.
- Kudva YC, **Henderson R**, **Kanapka L**, Weinstock RS, Rickels M, Pratley RE, Chaytor N, Janess K, Desjardins D, Pattan V, Peleckis AJ, Casu A, Rizvi SR, Bzdick S, Whitaker KJ, Jo Kamimoto J, Miller K, **Beck R**. A randomized clinical trial of automated insulin delivery in elderly with T1D. Presented at the 84th Scientific Sessions of the American Diabetes Association, Orlando, FL, June 2024.
- **Li Z**, **Beck R**, Durnwald C, Carlson A, Norton E, Bergenstal R, Johnson M, Dunnigan S, Banfield M, Krumwiede K, **Sibayan J**, **Calhoun P**. Continuous glucose monitoring prediction of gestational diabetes mellitus and adverse pregnancy outcomes. Presented at the 84th Scientific Sessions of the American Diabetes Association, Orlando, FL, June 2024.
- **Calhoun P**, **Beck RW**, **Li Z**, Peers S, Riddell M, Sherr J, Liggins RT. Percent time below 54 mg/dL is strongly associated with the number of weekly clinically significant level 2 hypoglycemia events in type 1 diabetes (T1D). Presented at the Diabetes Technology Society 24th Annual Diabetes Technology Meeting, Burlingame, CA, October 2024.

Eye Disease Studies

Published and Accepted Manuscript

- 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. Nat Commun 2024; in press.

Presentations

- Yavuz Saricay L, Jurkunas U. One-year changes in the central cornea on anterior segment OCT and in vivo confocal microscopy in eyes with limbal stem cell deficiency receiving cultivated autologous limbal epithelial cell (CALEC) transplantation. Presented at the American Society of Cataract and Refractive Surgery Annual Meeting, Boston, MA, April 2024.
- Jurkunas U, Kaufman AR, Yin J, **Ayala AR, Maguire M, Samarakoon L**, Johns LK, Parekh M, Li S, 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. Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Seattle, WA, May 2024.
- Jurkunas U, Kaufman AR, Yin J, **Ayala AR, Maguire M, Samarakoon L**, Johns LK, Parekh M, Li S, Gauthier A, Hernandez Rodriguez DE, Daley H, Dana R, Armant M, Ritz J. Cultivated autologous limbal epithelial cell (CALEC) transplantation for limbal stem cell deficiency. Presented at the Cornea and Eye Banking Forum, Chicago, IL, October 2024.
- Yavuz Saricay L, Jurkunas U. One-year changes in the central cornea on anterior segment OCT and in vivo confocal microscopy in eyes with limbal stem cell deficiency receiving cultivated autologous limbal epithelial cell (CALEC) transplantation. Presented at the American Academy of Ophthalmology Annual Meeting, Chicago, IL, October 2024.
- Yavuz Saricay L, Kaufman AR, Johns LK, Yin J, **Samarakoon L, Ayala A, Maguire M**, Parekh M, Hernandez Rodriguez DE, Daley H, Dana R, Armant M, Ritz J, Jurkunas UV. One-year changes in the central cornea on anterior segment OCT and in vivo confocal microscopy in eyes with limbal stem cell deficiency receiving cultivated autologous limbal epithelial cell (CALEC) transplantation. Presented at the Harvard 33rd Biennial Cornea Conference, Lisbon, Portugal, October 2024.

Appendix A: Staff Activities and Recognitions

Ayala, Allison R.

- Journal Reviewer: Investigative Ophthalmology & Visual Science

Bauza, Colleen E.

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

Beaulieu, Wesley T.

- Journal Reviewer: JAMA Ophthalmology; Retina; Ophthalmology Science; American Journal of Ophthalmology; British Journal of Ophthalmology
- Methodologist, American Academy of Ophthalmology Ophthalmic Technology Assessment Committee Retina/Vitreous Panel

Beck, Roy W.

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

Calhoun, Peter M.

- Grant Reviewer: Breakthrough T1D
- Journal Reviewer: Diabetologia, Diabetes Obesity and Metabolism; eClinicalMedicine, JAMA Open Network, JAMA Ophthalmology, Journal of Diabetes and its Complications
- Member, DSMB, ABC-WIT Study

Chandler, Danielle L.

- Peer Reviewer: American Journal of Ophthalmology

Gal, Robin L.

- Grant Reviewer: Breakthrough T1D
- Featured Presenter: Breakthrough T1D Diversity and Inclusion Coordinator Summit
- Host and Presenter: The Leona M. and Harry B. Charitable Trust Exercise Workshop
- Advisor and Contributing Member: INSPIRE T1D

Glassman, Adam R.

- Advisory Board Member: Cochrane Eye and Vision
- Editorial Board Member: JAMA Ophthalmology, Retina
- Grant Reviewer: National Eye Institute (NEI), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Breakthrough T1D
- Journal Reviewer: JAMA Ophthalmology, Ophthalmology, Ophthalmology-Retina, Retina, New England Journal of Medicine

Henderson, Robert J.

- Grant reviewer, NIDDK (x2)
- 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: JAMA Ophthalmology; Ophthalmology
- Grant Reviewer: Breakthrough T1D

Lum, John W.

- Board Member: Breakthrough T1D Tampa Bay Chapter
- Journal Reviewer: Diabetes Technology and Therapeutics

Melia, Michele

- Chair, Data and Safety Monitoring Committee, Zoster Eye Disease Study (ZEDS)
- Grant Reviewer: NIDCD
- Journal Reviewer: JAMA Ophthalmology

Sibayan, Judy

- Grant Reviewer: Breakthrough T1D

Stockdale, Cynthia R.

- Journal Reviewer: JAMA Ophthalmology

Appendix B: Grants and Sub-Awards Active During 2024

Cystic Fibrosis Foundation (CFF)

- **A Randomized Trial of the Insulin-only Bionic Pancreas in Cystic Fibrosis Related Diabetes (BP CFRD Main)**
 Principal Investigator: Colleen Bauza, PhD, MPH
 Funded through May 2026
- **CFRD BP Multicenter Trial Planning Grant (BP CFRD Planning)**
 Subaward through Mass General Brigham
 Principal Investigator: Colleen Bauza, PhD, MPH
 Ended October 2024
- **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 April 2024
- **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
 Funded through August 2026

Foundation Fighting Blindness (FFB)

- **Consortium Coordinating Center Core Efforts**
 Principal Investigator: Allison Ayala
 Funded through June 2029
- **Gyrate Atrophy Ocular and Systemic Study (GYROS)**
 Principal Investigator: Allison Ayala
 Funded through August 2027

- **Rate of Progression in EYS-Related Retinal Degeneration (Pro-EYS)**
Principal Investigator: Allison Ayala
Funded through December 2026
- **Rate of Progression in PCDH15-Related Retinal Degeneration (RUSH1F)**
Principal Investigator: Allison Ayala
Funded through December 2026
- **Rate of Progression in USH2A-Related Retinal Degeneration (RUSH2A)**
Principal Investigator: Allison Ayala
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
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
- **CGM Monitoring of Maternal Dysglycemia (GLAM)**
Joint funding with Savvysherpa, LLC (United Health Group)
Principal Investigator: Judy Sibayan, MPH
Ended January 2024
- **Economic Analysis of Automated Insulin Delivery (AID) Systems**
Subaward through University of Michigan
Principal Investigator: Roy W. Beck, MD, PhD
Ended December 2024
- **Educational Intervention to Support Diabetes Guidance for Exercise (EDGE)**
Principal Investigator: Robin Gal, MSPH
Funded through June 2025
- **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 January 2028
- **Exercise in Diabetes Initiative: Large Adult Study (T1-DEXI3)**
Joint funding with DexCom, Inc.
Principal Investigator: Robin Gal, MSPH
Ended April 2024

- **Exercise in Diabetes Initiative: Pediatrics Study (T1-DEXIP)**
Principal Investigator: Robin Gal, MSPH
Funded through February 2025
- **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 2025

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 August 2024
- **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 July 2025
- **CGMs in Prevention**
Principal Investigator: Peter Calhoun, PhD
Funded through January 2025
- **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: Colleen Bauza, PhD, 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: Colleen Bauza, PhD, MPH
Funded through August 2025

National Institutes of Health (NIH)

- **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)**
Principal Investigator: Robert Henderson, MS
Ended October 2024
- **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
- **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: Colleen Bauza, PhD, MPH
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
- **Safety and Feasibility of Cultivated Autologous Limbal Epithelial Cell (CALEC) Transplantation in the Treatment of Limbal Stem Cell Deficiency**
Principal Investigator: Allison Ayala
Ended June 2024

- **Translation of the UVA Advanced Automated Insulin Delivery Systems to Clinical Care in Young Children: Glycemic Control, Regulatory Acceptance and Optimization of Day-to-Day Use (PEDAP)**
 Joint funding with Tandem Diabetes Care, Inc. and subaward through the University of Virginia
 Principal Investigator: John Lum, MS
 Ended June 2024

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 Multicenter, Pivotal, Randomized Trial Comparing the Safety and Efficacy of an Automated Insulin Delivery System with Standard of Care in Adults with Type 2 Diabetes (EMBRACE-T2D)**
 Funding from Embecta Medical I LLC
 Principal Investigator: Colleen Bauza, PhD, MPH
- **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 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
 Principal Investigator: Thomas Mouse
- **An Observational Study of Adults with Type 2 Diabetes Using the Community-Derived Open-Source Automated Insulin Delivery (OS-AID) Loop System: Loop T2D Observational Study (T2D Loop)**
 Funding from Embecta Medical I LLC
 Principal Investigator: Colleen Bauza, PhD, MPH
- **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 Jaeb Center for Health Research Foundation, Inc.
- **CGM Monitoring of Maternal Dysglycemia (GLAM)**
 Funding from Savvysherpa, LLC
 Principal Investigator: Judy Sibayan, MPH

- **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 an Advanced Hybrid Closed Loop System Using Lyumjev with the Tandem t:slim X2 with Control-IQ in Adults, Adolescents and Children with Type 1 Diabetes (TL1)**
 Funding from Tandem Diabetes Care, Inc.
 Principal Investigator: John Lum, MS
- **Study of Preconception Food Security, Glycemia, and Nutrition (SPOON) CGM Data Management and Analysis**
 Funding from Jaeb Center for Health Research Foundation, Inc.
 Principal Investigator: Judy Sibayan, MPH
- **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 2024 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 2024 was incomplete. Accordingly, the numbers reflected here are unaudited. The final audited numbers may vary slightly.

Jaeb Center for Health Research and Affiliate Summary Financial Information Fiscal Year 2024			
Assets	\$56,921,982	Revenues	\$53,426,263
Liabilities	\$25,337,258	Expenses	\$50,466,270
Net Assets	\$31,584,724	Change in Net Assets	\$2,959,993

The combined assets of \$56,921,982 increased year over year by \$8,809,935 or 18.3 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 \$25,337,258 increased year over year by \$5,849,941 or 30 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 \$31,584,724 increased year over year by \$2,959,993 or 10.3 percent.

Combined revenues of \$53,426,263 increased year over year by \$4,805,811 or 9.9 percent. The bulk of this increase results from an increase in non-government industry-related clinical trial revenue. Combined expenses of \$50,466,270 increased year over year by \$6,493,079 or 14.7 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 and payments to clinical sites for the conduct of research activities.