



# JAEB CENTER FOR HEALTH RESEARCH 2022 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 30<sup>th</sup> year of operations.

JCHR was very productive in 2022. It continued to focus its research efforts on eye diseases and diabetes while also planning for studies in cystic fibrosis to begin in 2023. During 2022, JCHR had 49 active clinical studies. In addition to industry collaborations, JCHR received grants from the National Institutes of Health (8), Helmsley Charitable Trust (10), JDRF (5), Foundation Fighting Blindness (5), Cystic Fibrosis Foundation (2), and Food and Drug Administration (1). JCHR also self-funded one study and numerous statistical analysis projects using datasets from previously completed studies. 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), JDRF, Helmsley Charitable Trust, and Roche. Nine new grants, contracts, or subawards began during the year.

Among 2,859 entities receiving NIH funding in 2022, JCHR ranks in the top 9%. Out of 65,306 NIH grants provided in 2022, JCHR had the 173<sup>rd</sup> (top 0.3%) and 581<sup>st</sup> (top 0.9%) largest grants (source: Blue Ridge Institute for Medical Research, 2022).

JCHR projects had 62 manuscripts accepted or published and 53 presentations made at national and international meetings in 2022. Results from these manuscripts include the following four that were published in the New England Journal of Medicine:

- A randomized trial of bionic pancreas treatment in type 1 diabetes demonstrated that at 13 weeks, bionic pancreas use was associated with a greater reduction in HbA1c than standard care. Unlike currently available semiautomated insulin-delivery systems, the bionic pancreas does not require carbohydrate counting for routine operation.
- A randomized trial in very young children with type 1 diabetes (ages 1 to 7) showed improved glycemic control with the use of a hybrid closed-loop system (i.e., artificial pancreas) without increasing time spent in hypoglycemic range.
- A randomized trial in youths (10 to <17 years) with new onset type 1 diabetes demonstrated that hybrid closed-loop therapy did not prevent the decline of residual C-peptide secretion over 24 months compared with standard insulin treatment.

- A randomized trial in eyes with diabetic macular edema with moderate vision loss found no significant difference in visual acuity over two years between injections of aflibercept monotherapy (~\$1,830 per injection) and injections of bevacizumab first (~\$70 per injection) with a switch to aflibercept when there was suboptimal response.

In addition to conventional clinic-based clinical trials, JCHR conducted several “direct to-patient” studies in which JCHR staff had virtual contact with study participants who provided data via the Internet and from devices: (1) a study to collect device data during exercise in adults with type 1 diabetes; (2) a study to collect device data during exercise in youth with type 1 diabetes; (3) a study to provide virtual clinic support for adults with type 1 or type 2 diabetes that included support for the use of diabetes technology as well as behavioral health support; and (4) a study to collect real-world data from a diabetes management system that displays and tracks healthcare provider-recommended insulin dosing information.

In 2023, eye-disease projects will continue in three networks: DRCCR Retina Network, which studies diabetic retinopathy and other retinal diseases; Pediatric Eye Disease Investigator Network (PEDIG), which studies a range of eye diseases in children; and Foundation Fighting Blindness Consortium, which researches retinitis pigmentosa and other rare retinal diseases. DRCCR Retina Network and PEDIG are funded on 5-year grant cycles, both of which conclude at the end of 2023. However, both submitted grant renewal applications in 2022 for funding to continue from 2024-2028. Both grants were favorably reviewed, and a funding decision is anticipated in early 2023. Additionally, two studies evaluating cornea transplant approaches are in progress.

JCHR’s involvement in diabetes studies continued to expand as it solidified its reputation as the premiere coordinating center worldwide for diabetes device studies. Artificial pancreas studies and CGM studies are funded by the National Institutes of Health (NIH), JDRF, Helmsley Charitable Trust, and companies.

Adam Glassman, as Executive Director, continued to lead JCHR’s team of 149 employees (total as of December 31, 2022). Roy W. Beck, MD, PhD, JCHR’s founder and previous Executive Director, has remained active as JCHR’s Medical Director and Chairman of the JCHR Board of Directors. JCHR’s staff grew 8% in 2022, which included the hiring of 29 new staff during the year. At the end of 2022, JCHR had 43 employees with a tenure of 10 or more years, with another six entering their 10<sup>th</sup> year in 2023. The majority of JCHR staff continue to work remotely as JCHR follows a home-centric work model.

With certainty, 2023 will be another busy and productive year for JCHR.

## Studies Active During 2022

**Note:** 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.

### Network Studies

#### DRCR Retina Network

- A Randomized Trial Evaluating Fenofibrate for Prevention of Diabetic Retinopathy Worsening (Protocol AF)
- A Randomized Trial of Low-Dose Bevacizumab Versus Laser for Type 1 Retinopathy of Prematurity (ROP3)
- Bevacizumab Treatment for Posterior Type 1 Retinopathy of Prematurity (ROP4)
- Genetics in Retinal Diseases Project
- Home OCT Monitoring System: Feasibility Study (Protocol AK)
- Intravitreal Anti-VEGF Treatment for Prevention of Vision Threatening Diabetic Retinopathy in Eyes at High Risk (Protocol W)
- Randomized Trial Comparing Immediate versus Deferred Surgery for Symptomatic Epiretinal Membranes (Protocol AM)
- Randomized Trial of Intravitreal Aflibercept versus Intravitreal Bevacizumab + Deferred Aflibercept for Treatment of Central-Involved Diabetic Macular Edema (Protocol AC)
- Vitreous Proteomics in Eyes with a Macular Hole (Protocol AJ)

#### Foundation Fighting Blindness Consortium

- Rate of Progression in EYS-related Retinal Degeneration (Pro-EYS)
- Rate of Progression in USH2A-related Retinal Degeneration (RUSH2A)
- Rate of Progression of PCDH15-Related Retinal Degeneration in Usher Syndrome 1F (RUSH1F)

#### Pediatric Eye Disease Investigator Group

- A Randomized Clinical Trial of Overminus Spectacle Therapy for Intermittent Exotropia (IXT5)
- A Randomized Clinical Trial to Evaluate Sequential vs. 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 of Low-Dose Bevacizumab Versus Laser for Type 1 Retinopathy of Prematurity (ROP3)
- A Randomized Trial to Evaluate Low-Dose Atropine as Treatment for Myopia (MTS1)
- Bevacizumab Treatment for Posterior 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 (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, 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)
- An Observational Study to Assess CGM Accuracy in the ICU in People Being Treated with Insulin
- Automated Insulin Delivery for INpatients with DysGlycemia (AIDING) Feasibility Study
- Bigfoot Unity Real World Study (BURST)
- CamAPS FX Human Factors Usability Testing
- Closed Loop from Onset in Type 1 Diabetes (CLOuD)
- Continuous Glucose Monitoring in T2D Basal Insulin Users (MOBILE)
- Control-IQ Technology in Individuals with Type 2 Diabetes (2IQ)



- Evaluation of Adhesives for an Investigational Dexcom Sensor (DEMAP)
- Evaluation of the Biomedical and Psychosocial Impact of Automated Closed Loop (Artificial Pancreas) Insulin Delivery in Women with Type 1 Diabetes During Pregnancy (AiDAPT)
- Glycemic Variability and Fluctuations in Cognitive Status in Adults with Type 1 Diabetes (GluCog)
- Hybrid Closed Loop and Verapamil for Beta Cell Preservation in New Onsets with T1D (CLVer)
- Pregnancy Intervention with a Closed-Loop System (PICLS) Study
- 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
- The Insulin-Only Bionic Pancreas Extension Study (IOBP2X)
- The Insulin-Only Bionic Pancreas Pivotal Trial: Testing the iLet in Adults and Children with Type 1 Diabetes (IOBP)
- 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
- 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)

## Additional Studies

- Diabetes Endothelial Keratoplasty Study: Impact of Diabetes on Corneal Transplant Success and Endothelial Cell Loss (DEKS)
- Glucose Levels Across Maternity (GLAM)
- Safety and Feasibility of Cultivated Autologous Limbal Epithelial Cell Transplantation in the Treatment of Limbal Stem Cell Deficiency (CALEC)
- Strength and Muscle Related Outcomes for Nutrition and Lung Functions in CF (STRONG-CF)
- Study of Preconception Food Security, Glycemia, and Nutrition (SPOON)

## Appendix A: Staff Activities and Recognitions

### Ayala, Allison R.

- Author: Ayala A. The Importance of Natural History Studies in Inherited Retinal Diseases. Retinal Disorders: Genetic Approaches to Diagnosis and Treatment 2: Cold Spring Harbor Perspectives in Medicine; 2023. In Press.

### Beaulieu, Wesley T.

- Journal Reviewer: JAMA Ophthalmology, Retina, PLOS ONE

### 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; Cell Metabolism
- Grant Reviewer: JDRF, NIDDK

### Calhoun, Peter M.

- Journal Reviewer: Diabetes Obesity and Metabolism; Diabetes Technology and Therapeutics

### 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), JDRF
- Journal Reviewer: JAMA Ophthalmology, Ophthalmology, Ophthalmology-Retina, Retina, New England Journal of Medicine

### Henderson, Robert J.

- Journal Reviewer: JAMA Ophthalmology

### Kollman, Craig R.

- Grant Reviewer, JDRF

**Kraker, Raymond T.**

- Journal Reviewer: JAMA Ophthalmology; Ophthalmology

**Li, Zhoukai**

- Journal Reviewer: JAMA Ophthalmology

**Liu, Danni**

- Journal Reviewer: JAMA Ophthalmology

**Lum, John W.**

- Board Member: JDRF Tampa Bay Chapter
- Journal Reviewer: BMJ Case Reports; Diabetes Technology and Therapeutics

**Melia, Michele**

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

**Sutherland, Desirae R.**

- Journal Reviewer: American Academy of Ophthalmology (AAO)

## Appendix B: JCHR Principal/Lead Investigators

### *Studies and Other Research Activities*

#### Ayala, Allison R.

- Rate of Progression in EYS-related Retinal Degeneration (Pro-EYS)
- Rate of Progression in USH2A-related Retinal Degeneration (RUSH2A)
- Rate of Progression of PCDH15-Related Retinal Degeneration in Usher Syndrome 1F (RUSH1F)
- Safety and Feasibility of Cultivated Autologous Limbal Epithelial Cell Transplantation in the Treatment of Limbal Stem Cell Deficiency (CALEC)

#### Bauza, Colleen E.

- Diabetes Endothelial Keratoplasty Study: Impact of Diabetes on Corneal Transplant Success and Endothelial Cell Loss (DEKS)
- Hybrid Closed Loop and Verapamil for Beta Cell Preservation in New Onsets with T1D (CLVer)

#### Calhoun, Claire T.

- Home OCT Monitoring System: Feasibility Study (DRCR Protocol AK)
- Immediate vs. Deferred Surgery for Symptomatic Epiretinal Membranes (Protocol AM)
- Randomized Trial Comparing Immediate versus Deferred Surgery for Symptomatic Epiretinal Membranes (Protocol AM)

#### Chandler, Danielle L.

- A Randomized Clinical Trial of Overminus Spectacle Therapy for Intermittent Exotropia (IXT5)
- 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)

**Gal, Robin L.**

- 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, 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)
- Glycemic Variability and Fluctuations in Cognitive Status in Adults with Type 1 Diabetes (GluCog)
- Pediatric Diabetes Consortium
- 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)

**Glassman, Adam R.**

- Genetics in Retinal Diseases Project (part of DRCR Retina Network)
- Randomized Trial of Intravitreal Aflibercept versus Intravitreal Bevacizumab + Deferred Aflibercept for Treatment of Central-Involved Diabetic Macular Edema (DRCR Protocol AC)

**Henderson, Robert J.**

- 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 of Low-Dose Bevacizumab Versus Laser for Type 1 Retinopathy of Prematurity (ROP3)
- Bevacizumab Treatment for Posterior Type 1 Retinopathy of Prematurity (ROP4)

**Kraker, Raymond T.**

- A Randomized Clinical Trial to Evaluate Sequential vs. Simultaneous Spectacles plus Patching (ATS22)
- 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)

**Lum, John W.**

- Control-IQ Technology in Individuals with Type 2 Diabetes (2IQ)
- 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
- 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)

**Mouse, Thomas J.**

- Bigfoot Unity Real World Study (BURST)
- Evaluation of Adhesives for an Investigational Dexcom Sensor (DEMAP)

**Preston, Carin M.**

- Vitreous Proteomics in Eyes with a Macular Hole (Protocol AJ)

**Ruedy, Katrina J.**

- Continuous Glucose Monitoring in T2D Basal Insulin Users (MOBILE)
- The Insulin-Only Bionic Pancreas Pivotal Trial: Testing the iLet in Adults and Children with Type 1 Diabetes (IOBP) and Extension Study
- The Insulin-Only Bionic Pancreas Extension Study (IOBP2X)

**Sibayan, Judy R.**

- An Observational Study to Assess CGM Accuracy in the ICU in People Being Treated with Insulin
- Automated Insulin Delivery for INpatients with DysGlycemia (AIDING) Feasibility Study
- CamAPS FX Human Factors Usability Testing
- Closed Loop from Onset in Type 1 Diabetes (CLOuD)
- Evaluation of the Biomedical and Psychosocial Impact of Automated Closed Loop (Artificial Pancreas) Insulin Delivery in Women with Type 1 Diabetes During Pregnancy (AiDAPT)
- Glucose Levels Across Maternity (GLAM)
- Pregnancy Intervention with a Closed-Loop System (PICLS) Study

- Strength and Muscle Related Outcomes for Nutrition and Lung Functions in CF (STRONG-CF)
- Study of Preconception Food Security, Glycemia, and Nutrition (SPOON)
- 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

**Stockdale, Cynthia R.**

- A Randomized Trial Evaluating Fenofibrate for Prevention of Diabetic Retinopathy Worsening (DRCR Protocol AF)
- Intravitreal Anti-VEGF Treatment for Prevention of Vision Threatening Diabetic Retinopathy in Eyes at High Risk (DRCR Protocol W)

## Appendix C: Grants and Sub-Awards Active During 2022

### Cystic Fibrosis Foundation (CFF)

- **Strength and Muscle Related Outcomes for Nutrition and Lung Function in CF (STRONG-CF)**  
Principal Investigator: Judy Sibayan  
Funded through May 2028
- **Strength and Muscle Related Outcomes for Nutrition and Lung Function in CF (STRONG-CF Planning)**  
Principal Investigator: Judy Sibayan  
Ended May 2022
- **Studying the Presence and Development of CFRD and its Complications with Targeted Recruitment of Underrepresented Minority Groups (SPECTRUM-CF Planning)**  
Principal Investigator: Judy Sibayan  
Funded through April 2023

### Foundation for Fighting Blindness (FFB)

- **Consortium Coordinating Center Core Efforts**  
Principal Investigator: Allison Ayala  
Funded through June 2024
- **Gyrate Atrophy Ocular and Systemic Study (GYROS)**  
Joint funding with Food and Drug Administration (FDA)  
Principal Investigator: Allison Ayala  
Funded through August 2026
- **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 2023
- **Universal Rare Gene Study (Uni-Rare)**  
Principal Investigator: Allison Ayala  
Funded through December 2028



## Helmsley Charitable Trust (HCT)

- **A Pilot Study to Assess the Effectiveness of Direct to Patient Initiation of CGM in Diabetes (ReCGM)**  
 Principal Investigator: Robin Gal  
 Ended August 2022
- **A Randomized, Double Masked, Vehicle-Controlled, Multiple Dose, Dose Escalation Study to Evaluate the Safety and Efficacy of Immunotherapy with Multiple Peptides (MultiPepT1De) in Subjects with New-Onset Type 1 Diabetes (iMMPepBeta)**  
 Subaward through King's College London  
 Principal Investigator: Colleen Bauza  
 Funded through April 2026
- **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)**  
 Subaward through AdventHealth  
 Principal Investigator: Robin Gal  
 Funded through December 2022, pending extension
- **CGM Monitoring of Maternal Dysglycemia (GLAM)**  
 Joint funding with Savvysherpa, LLC (United Health Group)  
 Principal Investigator: Judy Sibayan  
 Funded through January 2023
- **Economic Analysis of Automated Insulin Delivery (AID) Systems**  
 Subaward through University of Michigan  
 Principal Investigator: Roy Beck  
 Funded through December 2024
- **Evaluation of the Relationship of Glucose Metrics via Continuous Glucose Monitoring with Diabetic Retinopathy (part of DRCR Protocol AF)**  
 Joint funding with NIH, JDRF, and F. Hoffman-La Roche, Ltd.  
 Principal Investigator: Cynthia Stockdale  
 Funded through September 2026
- **Exercise in Diabetes Initiative: Large Adult Study (T1-DEXI3)**  
 Joint funding with DexCom, Inc.  
 Principal Investigator: Robin Gal  
 Funded through April 2023
- **Exercise in Diabetes Initiative: Pediatrics Study (T1-DEXIP)**  
 Principal Investigator: Robin Gal  
 Funded through December 2023

- **T1D Exchange Clinic Network Coordinating Center (HCTPh3)**  
Principal Investigator: Roy Beck  
Ended September 2022
- **Virtual Diabetes Specialty Clinic (VDiSC)**  
Principal Investigator: Robin Gal  
Funded through April 2023

## JDRF

- **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  
Funded through June 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  
Funded through December 2025
- **CGMs in Prevention**  
Principal Investigator: Peter Calhoun  
Funded through March 2024
- **Hybrid Closed Loop and Verapamil for Beta Cell Preservation in New Onsets with T1D (CLVer)**  
Subaward through the University of Minnesota  
Principal Investigator: Colleen Bauza  
Funded through November 2022, pending extension
- **JDRF T1D Coordinating Center (JDRF CC)**  
Principal Investigator: Judy Sibayan  
Funded through July 2023

## 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  
Funded through April 2023

- **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  
 Funded through July 2026
- **Diabetes Endothelial Keratoplasty Study: Impact of Diabetes on Corneal Transplant Success and Endothelial Cell Loss (DEKS)**  
 Principal Investigator: Colleen Bauza  
 Funded through March 2026
- **DRCR Retina Network (DRCR)**  
 Principal Investigator: Adam Glassman  
 Funded through December 2023, pending extension
- **Glycemic Variability and Fluctuations in Cognitive Status in Adults with Type 1 Diabetes (GluCog)**  
 Subaward through McLean Hospital  
 Principal Investigator: Robin Gal  
 Funded through March 2023
- **Pediatric Eye Disease Investigator Group (PEDIG)**  
 Principal Investigator: Raymond Kraker  
 Funded through December 2023, pending extension
- **Safety and Feasibility of Cultivated Autologous Limbal Epithelial Cell (CALEC) Transplantation in the Treatment of Limbal Stem Cell Deficiency**  
 Principal Investigator: Allison Ayala  
 Funded through June 2023
- **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)**  
 Subaward through the University of Virginia  
 Principal Investigator: John Lum  
 Funded through June 2023

## Other Funding Sources

- **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  
 Funded through January 2025

- **A Pilot Study Evaluating Short-Term Efficacy of Xiflam for Diabetic Macular Edema (DRCR Protocol AO)**  
 Funding from InflammX Therapeutics, Inc.  
 Principal Investigator: Cynthia Stockdale  
 Funded through December 2023
- **A Randomized Clinical Trial Evaluating Intravitreal Faricimab (6.0 mg) Injections or Fluocinolone Acetonide (0.19 mg) Intravitreal Implants vs. Observation for Prevention of Visual Acuity Loss due to Radiation Retinopathy (DRCR Protocol AL)**  
 Funding from Alimera Sciences, Inc.  
 Principal Investigator: Carin Preston  
 Funded through December 2029
- **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  
 Funded through March 2023
- **AIDING Feasibility Study**  
 Funding from Insulet Corporation  
 Principal Investigator: Judy Sibayan  
 Funded through December 2022
- **Bigfoot Unity Real World Study (BURST)**  
 Funding from Bigfoot Biomedical, Inc.  
 Principal Investigator: Thomas Mouse  
 Funded through April 2024
- **Continuous Glucose Monitoring in T2D Basal Insulin Users (MOBILE)**  
 Funding from DexCom, Inc.  
 Principal Investigator: Katrina Ruedy  
 Funded through January 2022
- **Control-IQ Technology in Individuals with Type 2 Diabetes (2IQ)**  
 Funding from Tandem Diabetes Care, Inc.  
 Principal Investigator: John Lum  
 Funded through December 2022
- **Evaluation of Adhesives for an Investigational Dexcom Sensor (DEMAP)**  
 Funding from DexCom, Inc.  
 Principal Investigator: Thomas Mouse  
 Ended April 2022

- **Exploring Quantitative Measures Beyond HbA1c in Diabetes Drug Development Funding from Food and Drug Administration, subaward from Critical Path Institute**  
Principal Investigator: Roy Beck  
Funded through August 2022, pending extension
- **Intravitreal Anti-VEGF Treatment for Prevention of Vision Threatening Diabetic Retinopathy in Eyes at High Risk (DRCR Protocol W)**  
Funding from Regeneron Pharmaceuticals, Inc.  
Principal Investigator: Adam Glassman  
Funded through December 2023
- **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  
Funded through July 2023
- **Study of Preconception Food Security, Glycemia, and Nutrition (SPOON) CGM Data Management and Analysis**  
Funding from Jaeb Center for Health Research Foundation, Inc.  
Research Account  
Principal Investigator: Judy Sibayan  
Funded through March 2023
- **The Insulin-Only Bionic Pancreas Pivotal Trial: Testing the iLet in Adults and Children with Type 1 Diabetes (IOBP, IOBP Extension)**  
Funding from Beta Bionics, Inc.  
Principal Investigator: Roy Beck  
Funded through September 2022
- **Time In Glucose Hospital Target (TIGHT RCT and TIGHT ICU)**  
Funding from DexCom, Inc.  
Principal Investigator: Judy Sibayan  
Funded through March 2023

## Appendix D: Manuscripts and Presentations

**Note:** JCHR employees appear in boldface type.

### DRCR Retina Network

#### Published and Accepted Manuscripts

- Baker CW, **Josic K**, **Maguire MG**, Jampol LM, Martin DF, Rofagha S, Sun JK, for the DRCR Retina Network. Comparison of Snellen visual acuity measurements in retinal clinical practice to ETDRS protocol visual acuity assessment. Accepted 2022. *Ophthalmology*.
- Hutton DW, **Glassman AR**, **Liu D**, Sun JK, for the DRCR Retina Network. Cost-effectiveness of aflibercept monotherapy versus bevacizumab-first followed by aflibercept if needed for diabetic macular edema. Accepted 2022. *JAMA Ophthalmol*.
- Jhaveri CD, **Glassman AR**, Ferris FL, Liu D, Maguire MG, Allen JB, Baker CW, Browning D, Cunningham MA, Friedman SM, Jampol LM, Marcus DM, Martin DF, **Preston CM**, **Stockdale CR**, Sun JK, DRCR Retina Network. Aflibercept monotherapy versus bevacizumab first followed by aflibercept if needed for treatment of center-involved diabetic macular edema. *NEJM*. Published online July 14, 2022. DOI: 10.1056/NEJMoa2204225.
- Marcus DM, Silva PS, **Liu D**, Aiello LP, Antoszyk A, Elman M, Friedman S, **Glassman AR**, Googe JM, Jampol LM, Martin DF, **Melia M**, **Preston CM**, Wykoff CC, Sun JK; DRCR Retina Network. Association of predominantly peripheral lesions on ultra-widefield imaging and the risk of diabetic retinopathy worsening over time. *JAMA Ophthalmol*. Published online August 18, 2022. doi:10.1001/jamaophthalmol.2022.3131.
- Silva PS, **Liu D**, **Glassman AR**, Aiello LP, Grover S, Kingsley RM, **Melia M**, Sun JK, DRCR Retina Network. Assessment of fluorescein angiography nonperfusion in eyes with diabetic retinopathy using ultrawide field retinal imaging. *Retina*. 2022 Jul 1;42(7):1302-1310. doi: 10.1097/IAE.0000000000003479.
- Silva PS, Marcus DM, **Liu D**, Aiello LP, Antoszyk A, Elman M, Friedman S, **Glassman AR**, Googe JM, Jampol LM, Martin DF, **Melia M**, **Preston CM**, Wykoff CC, Sun JK; DRCR Retina Network. Association of ultra-widefield fluorescein angiography-identified retinal nonperfusion and the risk of diabetic retinopathy worsening over time. *JAMA Ophthalmol*. Published online August 18, 2022. doi:10.1001/jamaophthalmol.2022.3130.
- Sun JK, **Beaulieu WT**, **Melia M**, Ferris FL, Maturi RK, Nielsen JS, Solomon SD, Jampol LM, for the DRCR Retina Network. Defining “strong” versus “weak” response to anti-VEGF treatment for center-involved diabetic macular edema. Accepted 2022. *Retina*.

## Presentations

- Baker C. Comparison of routine visual acuity measurements in retinal clinical practice to ETDRS protocol VA. Presented at the American Academy of Ophthalmology annual meeting, Miami, FL, May 2022.
- **Glassman A.** Intravitreal aflibercept for prevention of vision threatening complications of diabetic retinopathy (Protocol W). Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Denver, CO, May 2022.
- Jhaveri C. Aflibercept monotherapy versus initial bevacizumab followed by aflibercept if needed for treatment of center-involved diabetic macular edema. Presented at the American Academy of Ophthalmology annual meeting, Miami, FL, May 2022.
- Kim J. A pilot study evaluating photobiomodulation therapy for DME (Protocol AE). Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Denver, CO, May 2022.
- **Maguire M.** Comparison of routine visual acuity measurements in retinal clinical practice to ETDRS protocol VA. Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Denver, CO, May 2022.
- Marcus D. Peripheral diabetic retinopathy lesions on UWF images and risk of diabetic retinopathy worsening over time (Protocol AA). Presented at the American Academy of Ophthalmology annual meeting, Miami, FL, May 2022.
- Marcus D. Peripheral diabetic retinopathy lesions on UWF images and risk of diabetic retinopathy worsening over time (Protocol AA). Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Denver, CO, May 2022.
- Silva P. Association of predominantly peripheral lesions on ultrawide field imaging and the risk of diabetic retinopathy worsening over time: results from DRCR Retina Network (Protocol AA). Presented at the American Academy of Ophthalmology annual meeting, Miami, FL, May 2022.
- Silva P. Association of predominantly peripheral lesions on ultrawide field imaging and the risk of diabetic retinopathy worsening over time: results from DRCR Retina Network (Protocol AA). Presented at the European Association for Diabetic Eye Complications Annual Meeting, Belfast, Ireland, May 2022.
- Silva P. UWF-FA nonperfusion and risk of diabetic retinopathy disease worsening over time (Protocol AA). Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Denver, CO, May 2022.
- Sun J. DME treatment response with anti-VEGF. Presented at the American Academy of Ophthalmology annual meeting, Miami, FL, May 2022.

- Sun J. DME treatment response with anti-VEGF. Presented at the Association for Research in Vision and Ophthalmology Annual Meeting, Denver, CO, May 2022.
- Martin D. Comparison of routine visual acuity measurements in retinal clinical practice to ETDRS (Protocol VA). Presented at the 45<sup>th</sup> Annual Macula Society Meeting, Berlin, Germany, June 2022.
- Silva P. UWF-FA nonperfusion and risk of diabetic retinopathy disease worsening over time (Protocol AA). Presented at the 45<sup>th</sup> Annual Macula Society Meeting, Berlin, Germany, June 2022.
- Sun J. Peripheral diabetic retinopathy lesions on UWF images and risk of diabetic retinopathy worsening over time (Protocol AA). Presented at the 45<sup>th</sup> Annual Macula Society Meeting, Berlin, Germany, June 2022.
- Jhaveri C. Aflibercept monotherapy versus initial bevacizumab followed by aflibercept if needed for treatment of center-involved diabetic macular edema. Presented at the American Society of Retina Specialists 40<sup>th</sup> Annual Scientific Meeting, New York, NY, July 2022.
- Marcus D. Peripheral diabetic retinopathy lesions on UWF images and risk of diabetic retinopathy worsening over time (Protocol AA). Presented at the American Society of Retina Specialists 40<sup>th</sup> Annual Scientific Meeting, New York, NY, July 2022.
- Silva P. Association of predominantly peripheral lesions on ultrawide field imaging and the risk of diabetic retinopathy worsening over time: results from DRCR Retina Network (Protocol AA). Presented at the American Society of Retina Specialists 40<sup>th</sup> Annual Scientific Meeting, New York, NY, July 2022.
- Antoszyk A. UWF-FA nonperfusion and risk of diabetic retinopathy disease worsening over time (Protocol AA). Presented at The Retina Society 54<sup>th</sup> Annual Scientific Meeting, Pasadena, CA, November 2022.
- Friedman S. Aflibercept monotherapy versus initial bevacizumab followed by aflibercept if needed for treatment of center-involved diabetic macular edema. Presented at The Retina Society 54<sup>th</sup> Annual Scientific Meeting, Pasadena, CA, November 2022.
- Marcus D. Peripheral diabetic retinopathy lesions on UWF images and risk of diabetic retinopathy worsening over time (Protocol AA). Presented at The Retina Society 54<sup>th</sup> Annual Scientific Meeting, Pasadena, CA, November 2022.
- Maturi R. Intravitreal aflibercept for prevention of vision threatening complications of diabetic retinopathy (Protocol W). Presented at The Retina Society 54<sup>th</sup> Annual Scientific Meeting, Pasadena, CA, November 2022.
- Nielsen J. DME treatment response with anti-VEGF. Presented at The Retina Society 54<sup>th</sup> Annual Scientific Meeting, Pasadena, CA, November 2022.



- Rofagha S. Comparison of routine visual acuity measurements in retinal clinical practice to ETDRS (Protocol VA). Presented at The Retina Society 54<sup>th</sup> Annual Scientific Meeting, Pasadena, CA, November 2022.

## Foundation Fighting Blindness Consortium

### Published and Accepted Manuscripts

- Hufnagel RB, **Liang W**, Duncan JL, Brewer CC, Audo I, **Ayala AR**, Branham K, Cheetham JK, Daiger SP, Durham TA, Guan B, Heon E, Hoyng CB, Iannaccone A, Kay CN, Michaelides M, Pennesi ME, Singh MS, Ullah E; Foundation Fighting Blindness Consortium Investigator Group. Tissue-specific genotype-phenotype correlations among USH2A-related disorders in the RUSH2A study. *Hum Mutat.* 2022 May;43(5):613-624. doi: 10.1002/humu.24365. Epub 2022 Mar 21. PMID: 35266249; PMCID: PMC9018588.
- Lad EM, Duncan JL, **Liang W**, **Maguire MG**, **Ayala AR**, Audo I, Birch DG, Carroll J, Cheetham JK, Durham TA, Fahim AT, Loo J, Deng Z, Mukherjee D, Heon E, Hufnagel RB, Guan B, Iannaccone A, Jaffe GJ, Kay CN, Michaelides M, Pennesi ME, Vincent A, Weng CY, Farsiu S; Foundation Fighting Blindness Consortium Investigator Group. Baseline Microperimetry and OCT in the RUSH2A Study: Structure-Function Association and Correlation With Disease Severity. *Am J Ophthalmol.* 2022 Dec;244:98-116. doi: 10.1016/j.ajo.2022.08.013. Epub 2022 Aug 22. PMID: 36007554; PMCID: PMC9712171.

### Presentations

- Stingl K. RUSH1F updates. Presented at the Usher 1 F Virtual Conference, (virtual), October 2022.
- Duncan JL. Static perimetry over two years in the RUSH2A study: Annual rates of change from mixed effects modeling. Presented at the Association for Research in Vision and Ophthalmology annual meeting (virtual), May 2022.
- Duncan JL. Accelerating research in rare inherited retinal disorders (IRDs) through an international consortium. Presented at the Scientific Medical Advisory Board of Retina International, Association for Research in Vision and Ophthalmology annual meeting, Denver, CO, May 2022.
- **Cheng P**, Birch DG, Duncan JL, Ferris FL, **Maguire MG**, **Ayala AR**, Cheetham JK, Durham TA, Fahim AT, Huckfeldt RM, Michaelides M, Pennesi ME, Sahel JA, Stingl K, Vincent A, Weng CY. Visual acuity and full-field stimulus thresholds (FST) over two years in the RUSH2A study: Annual rates of change from mixed effects modeling. Presented at the Association for Research in Vision and Ophthalmology annual meeting (virtual), May 2022.

- Vincent A, Lad EM. Microperimetry and optical coherence tomography measures over two years in the RUSH2A study: Annual rates of change from mixed effects modeling. Presented at the Association for Research in Vision and Ophthalmology annual meeting, Denver, CO, May 2022.
- Duncan JL, Accelerating research in rare inherited retinal disorders (IRDs) through an international consortium. Presented at the American Academy of Ophthalmology, Chicago, IL, October 2022.
- Pennesi M. Static perimetry in the rate of progression in USH2A-related retinal degeneration (RUSH2A) study: Assessment through two years. Presented at the Retina Society, Pasadena, CA, November 2022.
- **Ayala A.** Accelerating research in REDs through an international consortium. Presented at the ERN-EYE scientific workshop, Ghent, Belgium, December 2022.

## Pediatric Eye Disease Investigator Group

### Published and Accepted Manuscripts

- Bothun ED, Repka MX, **Kraker RT, Wu R**, Leske DA, Hatt SR, **Li Z**, Freedman SF, Astle WF, Cotter SA, Holmes JM. Incidence of glaucoma-related adverse events in the first five years after pediatric lensectomy. *JAMA Ophthalmol* 2022 [Accepted, In Press].
- Erzurum SA, **Wu R, Melia BM, Li Z**, Arnold RW, Silbert DI, Erickson JW, Sala NA, **Kraker RT**, Holmes JM, Cotter SA. Parent provided photographs as an outcome measure for childhood chalazia. *J AAPOS* 2022 Apr;26(2):60.e1-60.e5.
- Freedman SF, **Hercinovic A**, Wallace DK, **Kraker RT, Li Z**, Bhatt AR, Boente CS, Crouch ER, Hubbard GB, Rogers DL, VanderVeen D, Yang MB, Cheung NL, Cotter SA, Holmes JM. Low- and very low-dose bevacizumab for retinopathy of prematurity: Reactivations, additional treatments, and 12-month outcomes. *Ophthalmology* 2022;129(10):1120-1128.
- Hartnett ME, Wallace DK, **Dean TW, Li Z**, Boente CS, Dosunmu EO, Freedman SF, Golden RP, Kong L, Prakalapakorn SG, Repka MX, Smith LE, Wang H, **Kraker RT**, Cotter SA, Holmes JM. Plasma levels of bevacizumab and vascular endothelial growth factor after low-dose bevacizumab treatment for retinopathy of prematurity in infants. *JAMA Ophthalmol* 2022 Apr 1;140(4):337-344.
- Hatt SR, Leske DA, Holmes JM, **Henderson RJ, Chandler DL**, Morrison DG, Summers AI, Cotter SA. Testing depth of suppression in childhood intermittent exotropia. *J AAPOS* 2022 Feb;26(1):36-38.e1.

- Holmes JM, Leske DA, **Hercinovic A**, Hatt SR, **Chandler DL**, **Li Z**, **Melia BM**, Chen AM, Erzurum SA, Crouch ER, Jenewein EC, **Kraker RT**, Cotter SA. Rasch-calibrated intermittent exotropia symptom questionnaire for children. *Optom Vis Sci* 2022;99(6):513–520.
- Lorenzana IJ, Leske DA, Hatt SR, **Dean TW**, Jenewein EC, Dagi LR, Beal CJ, Pang Y, Retnasothie DV, Esposito CA, Erzurum SA, Aldrich AE, Crouch ER, **Li Z**, **Kraker RT**, Holmes JM, Cotter SA. Relationships among clinical factors and patient-reported outcome measures in adults with convergence insufficiency. *Optom Vis Sci* 2022;99(9):692-701.
- Manny RE, Holmes JM, **Kraker RT**, **Li Z**, Waters AL, Kelly KR, Kong L, Crouch ER, Lorenzana IJ, Alkharashi MS, Galvin JA, Rice ML, **Melia BM**, Cotter SA. A randomized trial of binocular Dig Rush game treatment for amblyopia in children aged 4 to 6 years of age. *Optom Vis Sci*. 2022 Mar 1;99(3):213-227.
- Pineles SL, **Henderson RJ**, Repka MX, Heidary G, Liu GT, Waldman AT, Borchert MS, Khanna S, Graves JS, Collinge JE, Conley JA, Davis PL, **Kraker RT**, Cotter SA, Holmes JM. The Pediatric Optic Neuritis Prospective Outcomes study – two-year results. *Ophthalmology* 2022 ;129(8):856-864.
- Repka MX, **Dean TW**, **Kraker RT**, **Li Z**, Yen KG, de Alba Campomanes AG, Young MP, Rahmani B, Haider KM, Whitehead GF, Lambert SR, Kurup SP, Kraus CL, Cotter SA, Holmes JM. Visual acuity and ophthalmic outcomes five years after cataract surgery among children younger than 13 years. *JAMA Ophthalmol*. 2022;140(3):269-276.
- Wallace DK, **Hercinovic A**, Freedman SF, Crouch ER, Bhatt AR, Hartnett ME, Yang MB, Rogers DL, Hutchinson AK, Good WV, Repka MX, **Li Z**, **Beck RW**, **Kraker RT**, Cotter SA, Holmes JM. Ocular and developmental outcomes of a dosing study of bevacizumab for retinopathy of prematurity. *J AAPOS* 2022 [Accepted, In Press].

### Presentations

- Bothun ED, Repka MX, **Kraker RT**, Leske DA, Hatt SR, **Li Z**, Freedman SF, Astle WF, Cotter SA, Holmes JM; on behalf of the Pediatric Eye Disease Investigator Group. Risk of developing glaucoma-related adverse event within five years following pediatric cataract surgery. Presented at the American Association for Pediatric Ophthalmology and Strabismus annual meeting, Scottsdale, AZ, March 2022.

- De Alba Campomanes AG, Repka MX, Leske DA, Hatt SR, Li Z, Morrison DG, **Kraker RT**, Holmes JM, Cotter SA; on behalf of the Pediatric Eye Disease Investigator Group. Myopic shift over five years following pediatric lensectomy with primary IOL implantation. Presented at the American Association for Pediatric Ophthalmology and Strabismus annual meeting, Scottsdale, AZ, March 2022.
- Galvin JA, Yen KG, Repka MX, **Sutherland DR**, **Kraker RT**, **Li Z**, Yoon HH, Haider KM, Hatt SR, Holmes JM, Cotter SA; on behalf of the Pediatric Eye Disease Investigator Group. Risk of complications within five years of primary intraocular lens (IOL) surgery for pediatric cataract. Presented at the American Association for Pediatric Ophthalmology and Strabismus annual meeting, Scottsdale, AZ, March 2022.
- Wallace DK, **Hercinovic A**, **Kraker RT**, Bhatt AR, Freedman SF, Crouch ER, Hutchinson AK, Hartnett ME, Yang MB, Rogers DL, Repka MX, Good WV, Cotter SA, Holmes JM; on behalf of the Pediatric Eye Disease Investigator Group. Two-year ocular and developmental outcomes of a phase 1 dosing study of bevacizumab for retinopathy of prematurity. Presented at the American Association for Pediatric Ophthalmology and Strabismus annual meeting, Scottsdale, AZ, March 2022.
- Chen AM, Erzurum SA, **Chandler DL**, **Hercinovic A**, Erickson JW, Vricella M, Ticho BH, Han S, Waters AL, McDowell PS, **Li Z**, **Kraker RT**, Holmes JM, Cotter SA; on behalf of the Pediatric Eye Disease Investigator Group. Three-year change in refractive error associated with overminus lens treatment for children with intermittent exotropia. Presented at the Association of Research in Vision and Ophthalmology annual meeting, Denver, CO, May 2022.
- Donahue SD, **Chandler DL**, **Wu R**, Law C, Areaux RG, Ghasia FF, Marsh JD, Esposito CA, **Li Z**, **Kraker RT**, Cotter SA, Holmes JM; on behalf of the Pediatric Eye Disease Investigator Group. Bilateral lateral rectus muscle recessions versus recess-resect for childhood intermittent exotropia (IXT): 8-year outcomes. Presented at the Association of Research in Vision and Ophthalmology annual meeting, Denver, CO, May 2022.
- Lorenzana IJ, Leske DA, Hatt SR, **Dean TW**, Jenewein EC, Dagi LR, Beal CJ, Pang Y, Retnasothie DV, Esposito CA, Erzurum SA, Aldrich AE, Crouch ER, **Li Z**, Holmes JM, Cotter SA; on behalf of the Pediatric Eye Disease Investigator Group. Relationships among clinical factors and patient-reported outcome measures of symptoms and quality of life in adults with convergence insufficiency. Presented at the Association of Research in Vision and Ophthalmology annual meeting, Denver, CO, May 2022.

- Haider KM, Repka MX, **Sutherland DR**, Hatt SR, Fallaha N, **Li Z**, **Kraker RT**, Holmes JM, Cotter SA; on behalf of the Pediatric Eye Disease Investigator Group. Visual acuity outcomes and complications five years after lensectomy for unilateral cataract associated with persistent fetal vasculature. Presented at the American Academy of Optometry annual meeting, San Diego, CA, October 2022.
- Wang SX, Repka MX, Hatt SR, Traboulsi EI, **Sutherland DR**, Lambert SR, Leske DA, **Li Z**, **Kraker RT**, Cotter SA, Holmes JM; on behalf of the Pediatric Eye Disease Investigator Group. Outcomes of secondary IOL implantation for pediatric aphakia. Presented at the American Academy of Ophthalmology annual meeting, Chicago, IL, October 2022.
- Wang SX, Repka MX, Hatt SR, Traboulsi EI, **Sutherland DR**, Lambert SR, Leske DA, **Li Z**, **Kraker RT**, Holmes JM, Cotter SA; on behalf of the Pediatric Eye Disease Investigator Group. Outcomes of secondary IOL implantation for pediatric aphakia. Presented at the American Academy of Optometry annual meeting, San Diego, CA, October 2022.

## A Validation Study of Home Blood Collection for HbA1c Measurement

### Published and Accepted Manuscript

- Jacobsen LM, **Bocchino LE**, **Lum JW**, **Kollman C**, **Barnes-Lomen V**, Sulik M, Haller MJ, Bode B, Cernich JT, Killeen AA, Garg U, Liljenquist D, Adams JG, Clements M, Gabrielson D, Johnson T, Clements MA, **Beck RW**. Accuracy of three commercial home-use hemoglobin A1c tests. *Diabetes Technol Ther*. 2022;24(11):789-96. Epub 2022/06/29. doi: 10.1089/dia.2022.0187. PubMed PMID: 35763337.

## Automated Insulin Delivery Amongst Pregnant Women with Type 1 Diabetes (AiDAPT)

### Published and Accepted Manuscript

- Lee TTM, Collett C, Man MS, Hammond M, Shepstone L, Hartnell S, Gurnell E, Byrne C, Scott EM, Lindsay RS, Morris D, Brackenridge A, Dover AR, Reynolds RM, Hunt KF, McCance DR, Barnard-Kelly K, Rankin D, Lawton J, **Bocchino LE**, **Sibayan J**, **Kollman C**, Wilinska ME, Hovorka R, Murphy HR; AiDAPT Collaborative Group. AiDAPT: Automated insulin delivery amongst pregnant women with type 1 diabetes: a multicentre randomized controlled trial - study protocol. *BMC Pregnancy Childbirth*. 2022 Apr 5;22(1):282. doi: 10.1186/s12884-022-04543-z. PMID: 35382796; PMCID: PMC8982306.

## Cornea Preservation Time Study

### Published and Accepted Manuscript

- Lass JH, **Bailey RJ**, Szczotka-Flynn LB, Benetz BA, Soper M, Titus MS, **Kollman C**, **Beck RW**; Cornea Preservation Time Study Group. Comparison of graft outcomes reusing original intermediate-term cold storage solution for entire corneal donor storage period with exchanged fresh storage solution after donor preparation in the Cornea Preservation Time Study. *Cornea*. 2022 Dec 1;41(12):1539-1544. doi: 10.1097/ICO.0000000000003108. Epub 2022 Sep 9. PMID: 36036663; PMCID: PMC9640289.

## Effect of Continuous Glucose Monitoring on Glycemic Control in Patients with Type 2 Diabetes Treated With Basal Insulin (MOBILE)

### Published and Accepted Manuscripts

- **Bailey R**, **Calhoun P**, Chao C, Walker TC. With or without residual C-Peptide, patients with type 2 diabetes realize glycemic benefits from real-time continuous glucose monitoring. *Diabetes Technol Ther*. 2022 Apr;24(4):281-284. doi: 10.1089/dia.2021.0384. Epub 2022 Mar 21. PMID: 34704817.
- Bao S, **Bailey R**, **Calhoun P**, **Beck RW**. Effectiveness of continuous glucose monitoring in older adults with type 2 diabetes treated with basal insulin. *Diabetes Technol Ther*. 2022 May;24(5):299-306. doi: 10.1089/dia.2021.0494. Epub 2021 Dec 22. PMID: 34939824; PMCID: PMC9127838.
- Davis G, **Bailey R**, **Calhoun P**, Price D, **Beck RW**. Magnitude of glycemic improvement in patients with type 2 diabetes treated with basal insulin: Subgroup analyses from the MOBILE study. *Diabetes Technol Ther*. 2022 May;24(5):324-331. doi: 10.1089/dia.2021.0489. Epub 2022 Apr 26. PMID: 34962151; PMCID: PMC9127836.

## Fuzzy Logic Automated Insulin Regulation (FLAIR)

### Published and Accepted Manuscripts

- Weinzimer SA, **Bailey RJ**, Bergenstal RM, Nimri R, **Beck RW**, Schatz D, Ambler-Osborn L, Schweiger DS, von dem Berge T, **Sibayan J**, Johnson ML, **Calhoun P**, Phillip M; FLAIR Study Group. A comparison of postprandial glucose control in the Medtronic Advanced Hybrid Closed-Loop System versus 670G. *Diabetes Technol Ther*. 2022 Aug;24(8):573-582. doi: 10.1089/dia.2021.0568. Epub 2022 Apr 28. PMID: 35363054; PMCID: PMC9353997.

- Dovic K, Battelino T, **Beck RW, Sibayan J, Bailey RJ, Calhoun P**, Turcotte C, Weinzimer S, Smigoc Schweiger D, Nimri R, Bergenstal RM. Impact of temporary glycemic target use in the Hybrid and Advanced Hybrid Closed-Loop Systems. *Diabetes Technol Ther.* 2022 Nov;24(11):848-852. doi: 10.1089/dia.2022.0153. Epub 2022 Aug 9. PMID: 35848991; PMCID: PMC9618368.

## International Diabetes Closed-Loop Study (iDCL)

### Published and Accepted Manuscripts

- Ekhlaspour L, **Raghinaru D**, Forlenza GP, Isganaitis E, Kudva YC, Lam DW, Levister C, O'Malley G, Church MM, **Lum JW**, Buckingham B, Brown SA. Outcomes in pump- and CGM-baseline use subgroups in the International Diabetes Closed-Loop (iDCL) trial. *J Diabetes Sci Technol.* 2022;19322968221089361. Epub 2022/04/28. doi: 10.1177/19322968221089361. PubMed PMID: 35473359.
- Ekhlaspour L, Town M, **Raghinaru D, Lum JW**, Brown SA, Buckingham BA. Glycemic outcomes in baseline hemoglobin A1C subgroups in the International Diabetes Closed-Loop Trial. *Diabetes Technol Ther.* 2022;27(8):588-91. Epub 2022/01/13. doi: 10.1089/dia.2021.0524. PubMed PMID: 35020488.
- Levy CJ, O'Malley G, **Raghinaru D**, Kudva YC, Laffel LM, Pinsker JE, **Lum JW**, Brown SA, iDCL Trial Research Group. Insulin delivery and glucose variability throughout the menstrual cycle on closed loop control for women with type 1 diabetes. *Diabetes Technol Ther.* 2022;24(5):357-61. Epub 2022/02/01. doi: 10.1089/dia.2021.0431. PubMed PMID: 35099294; PubMed Central PMCID: PMC9127830.
- Pinsker JE, Dassau E, Deshpande S, **Raghinaru D**, Buckingham BA, Kudva YC, Laffel LM, Levy CJ, Church MM, Desrochers H, Ekhlaspour L, Kaur RJ, Levister C, Shi D, **Lum JW, Kollman C**, Doyle FJ. Outpatient randomized crossover comparison of zone model predictive control automated insulin delivery with weekly data driven adaptation versus sensor-augmented pump: Results from the International Diabetes Closed-Loop Trial 4. *Diabetes Technol Ther.* 2022;24(9):635-42. Epub 2022/05/14. doi: 10.1089/dia.2022.0084. PubMed PMID: 35549708; PubMed Central PMCID: PMC9422791.



## 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)

### Published and Accepted Manuscript

- Wadwa RP, **Reed ZW**, Buckingham B, DeBoer MD, Ekhlaspour L, Forlenza G, Schoelwer M, **Lum J**, **Kollman C**, **Beck RW**, Breton M. Hybrid Closed Loop Randomized Trial in Young Children with Type 1 Diabetes. *N Engl J Med.* 2022; Accepted for publication.

### Presentation

- Breton, M. Results from the Pediatric Artificial Pancreas (PEDAP) clinical trial. Presented at the International Society for Pediatric and Adolescent Diabetes Conference, Abu Dhabi, United Arab Emirates, October 2022.

## The Insulin-Only Bionic Pancreas Pivotal Trial: Testing the iLet in Adults and Children with Type 1 Diabetes (IOBP)

### Published and Accepted Manuscripts

- **Beck RW**, Russell SJ, Damiano ER, El-Khatib FH, **Ruedy KJ**, Balliro C, **Li Z**, **Calhoun P**. A multicenter randomized trial evaluating fast-acting insulin aspart in the bionic pancreas in adults with type 1 diabetes. *Diabetes Technol Ther.* 2022;24(10):681-96. Epub 2022/09/30. doi: 10.1089/dia.2022.0167. PubMed PMID: 36173235; PubMed Central PMCID: PMC9529301.
- Kruger D, Kass A, Lonier J, Pettus J, Raskin P, Salam M, Trikudanathan S, Zhou K, Russell SJ, Damiano ER, El-Khatib FH, **Ruedy KJ**, Balliro C, **Li Z**, **Marak MC**, **Calhoun P**, **Beck RW**. A multicenter randomized trial evaluating the insulin-only configuration of the bionic pancreas in adults with type 1 diabetes. *Diabetes Technol Ther.* 2022 Oct;24(10):697-711. doi: 10.1089/dia.2022.0200. PMID: 36173236; PMCID: PMC9634987.
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- Balliro CA. Assessing the safety and feasibility of using the iLet with blood glucose measurements as the input. Presented at the American Diabetes Association 82<sup>nd</sup> Scientific Sessions, New Orleans, LA, June 2022.
- **Beck RW**, Forlenza G, Kruger D, Messer L, Buckingham B, Weissberg-Benchell J, Russell SJ. The insulin-only bionic pancreas pivotal trial: Randomized clinical trial results. Presented at the American Diabetes Association 82<sup>nd</sup> Scientific Sessions, New Orleans, LA, June 2022.
- Lynch JL. A multi-center extension study of the insulin-only configuration of the bionic pancreas in adults and youth with type 1 diabetes. Presented at the American Diabetes Association 82<sup>nd</sup> Scientific Sessions, New Orleans, LA, June 2022.
- Mauras N. Utility and safety of back-up insulin regimes generated by the bionic pancreas: A randomized study. Presented at the American Diabetes Association 82<sup>nd</sup> Scientific Sessions, New Orleans, LA, June 2022.
- Balliro C. Multicenter randomized trial of a bionic pancreas in adults and children with type 1 diabetes. Presented at the Association of Diabetes Care & Education Specialists Annual Conference, Baltimore, MD, August 2022.

## One-Year Day-and-Night Home Closed Loop in Young People with Type 1 Diabetes (DAN05)

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- Ware J, Boughton CK, Allen JM, Wilinska ME, Tauschmann M, Denvir L, Thankamony A, Campbell FM, Wadwa RP, Buckingham BA, Davis N, DiMeglio LA, Mauras N, Besser REJ, Ghatak A, Weinzimer SA, Hood KK, Fox DS, **Kanapka L, Kollman C, Sibayan J, Beck RW**, Hovorka R; DAN05 Consortium. Cambridge hybrid closed-loop algorithm in children and adolescents with type 1 diabetes: A multicentre 6-month randomized controlled trial. *Lancet Digit Health*. 2022 Apr;4(4):e245-e255. Doi: 10.1016/S2589-7500(22)00020-6. Epub 2022 Mar 7. PMID: 35272971.

## Pediatric Diabetes Consortium

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## Strategies to Enhance New CGM Use in Early Childhood Study (SENCE)

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- Hilliard ME, Commissariat PV, **Kanapka L**, Laffel LM, Levy W, Harrington K, Anderson BJ, Miller KM, DiMeglio LA. Development and delivery of a brief family behavioral intervention to support continuous glucose monitor use in young children with type 1 diabetes. *Pediatr Diabetes*. 2022. Epub 2022/04/22. doi: 10.1111/pedi.13349. PubMed PMID: 35446449.
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## Study to Assess Continuous Glucose Sensor Profiles in Healthy Non-Diabetic Subjects

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## T1D Exchange Registry

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- **Hughes MS, Bailey R, Calhoun P, Shah VN, Lyons SK, DeSalvo DJ.** Off-label use of sodium glucose co-transporter inhibitors among adults in Type 1 Diabetes Exchange Registry. *Diabetes Obes Metab.* 2022;24(1):171-173. doi:10.1111/dom.14556.
- **Mizokami-Stout K, Bailey R, Ang L, Aleppo G, Levy CJ, Rickels MR, Shah VN, Polsky S, Nelson B, Carlson AL, Vendrame F, Pop-Busui R.** Symptomatic diabetic autonomic neuropathy in type 1 diabetes (T1D): Findings from the T1D Exchange. *J Diabetes Complications.* 2022;36(5):108148. Epub 2022/03/14. doi: 10.1016/j.jdiacomp.2022.108148. PubMed PMID: 35279403.

## The Artificial Pancreas in Very Young Children With T1D (KidsAP02)

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- **de Beaufort C, Schierloh U, Thankamony A, Ware J, Wilinska ME, Fröhlich-Reiterer E, Kapellen TM, Rami-Merhar B, Hofer SE, Campbell FM, Yong J, Bocchino LE, Sibayan J, Lawton J, Roze S, Fritsch M, Thiele A, Allen JM, Boughton C, Mader JK, Kollman C, Hovorka R, Pit-Ten Cate IM; KidsAP Consortium.** Cambridge hybrid closed-loop system in very young children with type 1 diabetes reduces caregivers' fear of hypoglycemia and improves their well-being. *Diabetes Care.* 2022 Sep 16:dc220693. doi: 10.2337/dc22-0693. Epub ahead of print. PMID: 36350787.
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## An Open-label, Multicentre, Randomised, Single-period, Parallel Design Study to Assess the Effect of Closed Loop Insulin Delivery from Onset of Type 1 Diabetes in Youth on Residual Beta Cell Function Compared to Standard Insulin Therapy (CLOuD)

### Published and Accepted Manuscript

- Boughton CK, Allen JM, Ware J, Wilinska ME, Hartnell S, Thankamony A, Randell T, Ghatak A, Besser REJ, Elleri D, Trevelyan N, Campbell FM, **Sibayan J, Calhoun P, Bailey R**, Dunseath G, Hovorka R; CLOuD Consortium. Closed-loop therapy and preservation of C-peptide secretion in type 1 diabetes. *N Engl J Med*. 2022 Sep 8;387(10):882-893. doi: 10.1056/NEJMoa2203496. PMID: 36069870.

## Type 1 Diabetes Exercise Initiative (DEXI)

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## Virtual Diabetes Specialty Clinic: A Study Evaluating Remote Initiation of Continuous Glucose Monitoring (VDiSC)

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