IN FOCUS

SPRING/SUMMER 2024

RESEARCH ADVANCES

Beacon Therapeutics Reports Encouraging Interim Results from Phase 2 Clinical Trial for XLRP Gene Therapy

Beacon Therapeutics has reported vision improvements for five of eight patients receiving the high dose of its X-linked retinitis pigmentosa (XLRP) gene therapy in the Phase 2 SKYLINE clinical trial. Known as AGTC-501, the emerging gene therapy is for patients with mutations in RPGR, the gene most frequently associated with XLRP. Interim, 12-month results for SKYLINE were reported on February 7, 2024, by Mark Pennesi, MD, PhD, director, Ophthalmic Genetics, Retina Foundation of the Southwest, at the 47th Macula Society Meeting.

Vision improvements were measured using microperimetry, a test that measures light sensitivity at several loci (points) in the central retina. The test also captures retinal images. Five of eight patients responding to the high dose of AGTC-501 had improvements in retinal sensitivity of at least 7 decibels in 5 or more loci. Responses of the six patients receiving the low dose of the therapy were similar to untreated eyes in the high dose group.

AGTC-501 was well-tolerated, and no clinically significant safety events were associated with treatment.

Continued on page 2

A Publication for Members of the FOUNDATION FIGHTING BLINDNESS

WHAT'S INSIDE

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Cover Story

CONTINUED FROM FRONT COVER

The XLRP gene therapy was delivered by a one-time subretinal injection. AGTC-501 uses a human-engineered adeno-associated virus (AAV), which works like a vast container system, to deliver healthy copies of the RPGR gene to cells in the retina.

Beacon plans to launch its Phase 2/3 VISTA clinical trial for AGTC-501 during the first half of 2024.

The Foundation Fighting Blindness funded successful canine studies of XLRP gene therapy at the University of Pennsylvania School of Veterinary Medicine that helped make the XLRP gene therapy clinical trial possible.

XLRP affects approximately 20,000 people in the US and EU. As an X-linked condition, XLRP usually affects males. Though females are usually unaffected carriers of XLRP, they sometimes have vision loss, as well. The condition causes constriction of vision, reduced vision in dark settings, and central vision loss, especially in later stages. Most males with XLRP are legally blind by the age of 45.

VISIONS 2024

Join Us at VISIONS 2024, the Global Conference of the Foundation

Friday, June 21–Saturday, June 22, 2024
Chicago Marriott
Downtown Magnificent Mile

VISIONS 2024, the global conference of the Foundation Fighting Blindness, provides an excellent opportunity to connect with others from the blind and low vision community and learn about the latest research advancements, products, and services for members of our community.

The conference is designed specifically for individuals and families who are affected by blinding diseases such as retinitis pigmentosa, Usher syndrome, Stargardt disease, Leber congenital amaurosis, age-related macular degeneration, and other blinding diseases. More than 500 individuals in the blind and visually impaired community are expected to attend this informative and encouraging conference.

We're excited to announce that our Luncheon Keynote Speaker will be **Sumaira "Sam" Latif,** Senior Director, Company Accessibility Leader, and Global People with Disabilities Leader at Procter & Gamble.

You can hear from Sam and other inspirational speakers when you attend VISIONS 2024! To learn more details and to register, visit: **www.FightingBlindness.org/VISIONS2024**

Sam Latif is P&G's first Company Accessibility Leader – a role within which she is responsible for driving forward innovation to make the company's 65+ brands inclusive and accessible for the 15% of people around the globe who experience some form of disability.
Sam's passion for her work stems from her personal experiences. She was born with a rare genetic condition known as retinitis pigmentosa, meaning that by the age of 16, she had lost 97% of her sight. Unwilling to let anything stop her from achieving her dreams, Sam went on to have a hugely successful IT career within P&G, joining the company in 2000.

In 2015, Sam switched from running IT businesses to focusing on embedding accessibility into P&G, and in 2019, she was promoted to Senior Director, taking on the formal title of Company Accessibility Leader.

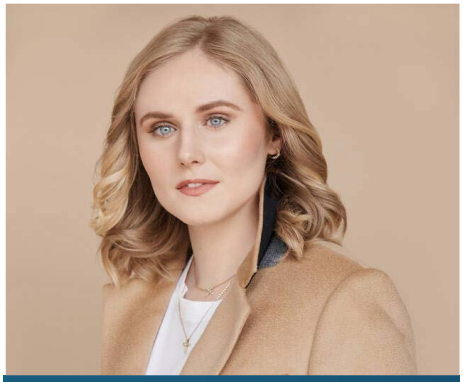
In recent years, she has inspired international audiences with her story: overcoming blindness, dealing with rejection, learning to be interdependent, forging a successful career and life in a world that wasn't designed with her in mind, being true to herself and her values, and finding compromises that work. She has developed an approach to making the world that is more inclusive for all. She has got there by living in a way that is patiently persistent and finds practical solutions that transform ways of working.

Sam loves to share her story with people who have a genuine interest in building more accessible and inclusive communities that make people feel that they belong. Although her story is unique, she finds that people resonate with her challenges and are left feeling inspired to make the differences that are within their power.

BEACON STORY

How an Assistive App Developer is Revolutionizing Accessibility

Meet Another VISIONS Speaker: Rebecca Rosenberg, Founder of ReBokeh Vision Technologies



Rebecca posing in front of a beige-colored backdrop.

Meet Rebecca Rosenberg, the founder of assistive technology startup ReBokeh Vision Technologies. From her diagnosis of oculocutaneous albinism (OCA1) at a young age, the engineering student turned CEO's journey has been quite unique. Now, at the age of 25, she stands at the forefront of revolutionizing assistive technology for those with moderately low vision.

Several months after birth, Rebecca accompanied her mother to a routine dental appointment. While in the doctor's office, the receptionist noticed some irregularities in her nystagmus due to her own family's history of blindness. After a few weeks, she reached out to Rebecca's parents, which led to a series of doctor visits and initial misdiagnosis. Rebecca was ultimately diagnosed with OCA1 and underwent strabismus surgery at the age of three.

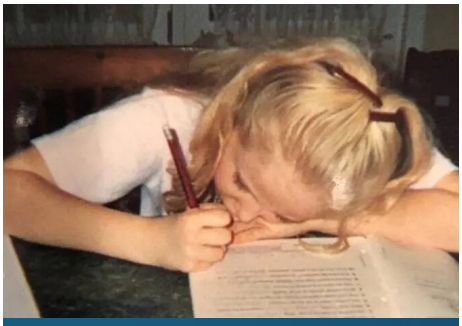
"It basically resulted in decreased visual acuity," says Rebecca. "The way I would describe it is if a regular sighted person sees in high definition, I see in standard definition. I'm missing pixels and a lot of them. I spent most of my life growing up not really sure if I was going to be able to get my driver's license."

Rebecca went on to pursue an undergraduate degree in biomedical engineering at Bucknell University in Pennsylvania. After graduating, she went to Johns Hopkins University to pursue a master's degree at the Center of Bioengineering Innovation and Design.

During her time at Johns Hopkins University, she actively participated in projects focused on global health. For one year, she led a project on the development of a tool designed to automatically classify mosquitoes based on photographs before transitioning to entrepreneurship full-time.

"There are a lot of qualities that you need to have to be an entrepreneur and to create something where nothing existed before," says Rebecca. "I think that the qualities that are embedded in a person who has lived with any type of disability include self-reliance, perseverance, risk-taking, and the understanding of how to deal with the loneliness of knowing that other people don't know what you are dealing with. All those things make a good entrepreneur, and people with disabilities are learning those things as children."

Rebecca's initial inspiration to start ReBokeh stemmed from her personal experience with albinism and the lack of assistive technology available for individuals between the vision spectrum.



A childhood photo of Rebecca writing in a book.

"The initial motivation was that there was nothing available for me, and I wanted to make something that would work for me," says Rebecca. "I managed to get a grant from my undergraduate university to take on that problem for a summer. By the end of the summer, I had less than a back of a napkin idea, but I felt that a smartphone app would make sense and be the right way to move forward."

Once news began to spread after a few local interviews, Rebecca recognized the importance of her idea to the visually impaired community. She dedicated herself to the project throughout her three years as a student, collaborating with fellow students and experts, leading to the establishment of ReBokeh Vision Technologies. Her expanding team has become a vital part of the development process, and user feedback has served as an integral part of shaping the app into what it is today.

The ReBokeh smartphone app is a modern assistive technology for individuals with low vision. Unlike conventional assistive tools such as tactile and audio descriptions, the app grants users the unique ability to utilize their camera feeds to modify the appearance of the world around them.

"For a year, ReBokeh was in beta with about 100 users and a full advisory board of people who were providing us feedback on everything from bugs to different capabilities people wanted to see it have in the future," Rebecca recalls.

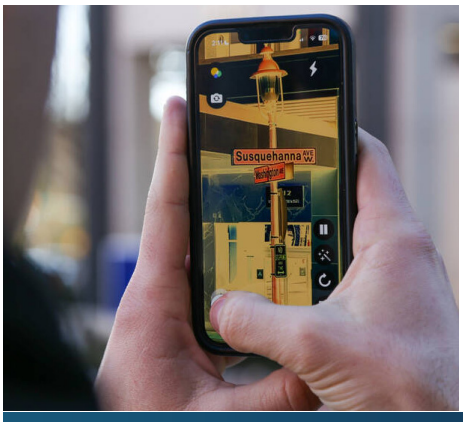
Since then, the company has expanded to include users in 96 countries and has recently launched ReBokeh Plus, their first premium subscription tier. ReBokeh Plus allows users access to tailored features, including expanded inversion options, the ability to upload and adjust images, and customizable presets to further adjust their experience to fit their unique needs.

While the company has achieved significant success, what truly fulfills Rebecca is the relationships she has cultivated with fellow entrepreneurs and the profound impact the app has had on the lives of visually impaired individuals who have had positive experiences using the app.

"People and relationships are so important as you go through this journey, especially because you can begin to help other people too," says Rebecca. "As I have had more experience as an entrepreneur, I've been able to help other entrepreneurs, and it's a really fun and rewarding cycle once you get into the startup world."

With significant plans for her company and high hopes for the future of assistive technology, Rebecca plans to expand further and leverage emerging technologies such as machine learning and artificial intelligence.

"I think we are really going to move to holding assistive technology companies to a higher standard in terms of the products that they are producing, especially at the price points that a lot of them tend to come in at," says Rebecca. "And I also think that as additional technology becomes available and shakes up the tech landscape as a whole, I'm hoping that we start to see that embedded into assistive technologies."



A closeup demonstrating the camera feed features of the ReBokeh app.

Experience ReBokeh live at VISIONS 2024, as there will be exclusive on-site access to the app!

CLINCIAL-TRIAL PIPELINE

Inherited Retinal Diseases and Dry AMD: 48 Trials (select)

GENE THERAPIES (GENE TARGET)	PROGRESS
Achromatopsia (CNGB3) – MeiraGTx/Janssen	Phase 1/2
Achromatopsia (CNGA3) – MeiraGTx/Janssen	Phase 1/2
Achromatopsia (CNGA3) – Tubingen Hosp	Phase 1/2
AMD- dry, GA (CD59) – Janssen	Phase 2
AMD- dry, GA (RORA) – Ocugen	Phase 1/2
AMD- dry, GA (CFH) – Perceive Bio	Phase 1/2
Batten disease (CLN5) – Neurogene	Phase 1/2
Choroideremia (REP1) – 4DMT	Phase 1/2
LCA (GUCY2D) – Atsena	Phase 1/2
LCA and RP (RPE65) – MeiraGTx/Janssen	Phase 1/2
LCA (LCA5, lebercillin) – Opus Genetics	Phase 1/2
RP (PDE6B) – Coave	Phase 1/2
RP (RLBP1) – Novartis	Phase 1/2
RP & LCA (NR2E3) – Ocugen	Phase 1/2
RP (RdCVF) – SparingVision	Phase 1/2
RP (PDE6A) – Tubingen Hosp	Phase 1/2
Retinoschisis (RS1) – Atsena	Phase 1/2
Retinoschisis (RS1) – NEI	Phase 1/2
Stargardt disease (RORA) – Ocugen	Phase 1/2
X- linked RP (RPGR) – Beacon	Phase 2
X- linked RP (RPGR) – MeiraGTx/Janssen	Phase 3
X- linked RP (RPGR) – 4DMT	Phase 1/2

RNA/OTHER THERAPIES (MECHANISM)	PROGRESS
AMD- dry, GA (CB inhibitor) – Ionis	Phase 2
LCA10 (AON targeting IVS26) – Sepul Bio	Phase 2/3
RP-P RPF31 (CNOT3) – PYC	Phase 1/2
RP, Usher, others (optogenetic) – Bionic Sight	Phase 1/2
RP, Usher, others (optogenetic) – GenSight	Phase 1/2
RP, Usher, others (optogenetic) – Nanoscope	Phase 2
Usher 2A (AON targeting exon 13) – Sepul Bio	Phase 2/3
Stargardt disease (optogenetic) – Nanoscope	Phase 2

CELL-BASED THERAPIES (CELL TYPE)	PROGRESS
AMD- dry, GA (RPE) – Astellas	Phase 1/2
AMD- dry, GA (RPE) – Lineage	Phase 1/2
AMD- dry, GA (RPE) – Luxa	Phase 1/2
AMD- dry, GA (RPE from iPSC) – NEI	Phase 1/2
AMD- dry, GA (RPE on scaffold) – Regen Patch	Phase 1/2
RP, Usher (retinal progenitors) – jCyte	Phase 2b
RP (CD34+ stem cells) – UC Davis	Phase 1

SMALL MOLECULES (MECHANISM)	PROGRESS
AMD- dry, GA (deuterated vit. A) – Alkeus	Phase 3
AMD- dry, GA (RBP4 inhibitor) – Belite Bio	Phase 3
RP (NAC- anti-oxidant) – Johns Hopkins	Phase 3
RP (methotrexate) – Aldeyra	Phase 2
RP (small molecule) – Endogena	Phase 1/2
RP (small molecule, photoswitch) – Kiora	Phase 1/2
Stargardt disease (deuterated vit A) – Alkeus	Phase 2
Stargardt disease (C5 inhibitor) – Astellas	Phase 2
Stargardt disease (anti- RBP4) – Belite Bio	Phase 3
Stargardt disease (metformin) – NEI	Phase 1/2
Usher syndrome (NACA-anti- oxidant) – Nacuity	Phase 1/2

Note: Some trials listed may have been paused and/or the sponsors are seeking partners to continue their trials.

For more details and trial contact information, visit **FightingBlindness.org/Clinical-Trial-Pipeline**
This document is for informational purposes only. Information is subject to change, and its accuracy cannot be guaranteed. Updated February 2024.

COMMUNITY SPOTLIGHTS

Vision Seminars

On February 24, 2024, the Foundation hosted two Vision Seminars in the Los Angeles and South Carolina regions. These free half-day seminars provided the latest information on age-related macular degeneration (AMD), with featured speakers sharing recent scientific advancements, current and upcoming clinical trials, treatment options, and more.

Thank you to the following speakers at the Los Angeles Vision Seminar:

- David S Boyer, MD, Retina-Vitreous Associates Medical Group
- Tina Mac Donald, OD CDCES, FAAO, Clinical Assistant Professor, Eye Care Institute at WesternU
- Sun Young Lee, MD, PhD, Assistant Professor of Ophthalmology and Physiology & Neuroscience, Keck School of Medicine of USC

And thank you to the speakers at the South Carolina Vision Seminar:

- Dr. Jeffrey Gross, MD, FASRS, Vitreoretinal Specialist, Partner-Palmetto Retina Center/Carolina Retina Center
- Dr. James F Hill III, OD, FAAO, Associate Professor/Medical Director of Optical Services
- Dr. Teresa Fowler, MD, MS, 4th year Ophthalmology Resident Medical College of Georgia, 2024 Vitreoretinal Surgery Fellowship, Palmetto Retina Center/Carolina Retina Center
- Chad Jackson, PhD, Senior Director, Preclinical Translational Research Program, Foundation Fighting Blindness

Chapter Leadership Training at VISIONS 2024

If you're involved as a chapter leader for the Foundation, we encourage you to join us the evening of Thursday, June 20, at VISIONS 2024 for Chapter Leadership Training! Foundation leaders can obtain group leadership training and connect with other leaders across the nation. To learn more, reach out to: **Chapters@FightingBlindness.org**

VISIONWALK SPOTLIGHT

End-of-Year Challenge

The Foundation Fighting Blindness' fall VisionWalk events came together in friendly competition in November and December 2023. The walk that raised the most post-Walk funds over those two months would win the challenge with prizes of a special treat at their 2024 VisionWalk and a feature in this InFocus newsletter edition. Congratulations to the Boston VisionWalk, which took first place in the challenge – raising over $50,000 in the last two months of 2023!

Overall, the 16th Annual Boston VisionWalk raised over $170,000 and celebrated with 27 teams and over 200 walkers. It was a beautiful day for a walk along the Charles River, and the day was fun-filled with costumed teams, community groups, a sponsor village, and an energetic kids' fun zone.

Foundation Board Member, Boston Chapter President, and VisionWalk Chair Martha Steele took the Year End Challenge idea and ran with it. By coordinating a local matching donor, highlighting the VisionWalk and Challenge in her post-walk messaging, and engaging the chapter leadership, Martha helped bring Boston to the top of the leaderboard.

"Success with the VisionWalk and growth in the chapter feed each other, and I'm excited that we are experiencing both this year in Boston," says Martha. "We've got so many plans for the coming year to keep up our momentum, and the promise of the treat at the VisionWalk this fall is just a sweet tribute to the hard work of our teams and walkers."

Registration for the 17th Annual Boston VisionWalk, along with our other 2024 VisionWalks across the country, is now underway. Find your local VisionWalk today at: **www.VisionWalk.org**

Volunteers from Boston University's chapter of Alpha Chi Alpha pose with the RedSox mascot by the Registration Tent.

Team Strides for Eagle Eyes (Left to right: Jane Connet, Bob Stymeist, Martha Steele, and Alvin) at the end of the VisionWalk.

Hannah and Charlotte LeBlanc of the Visionaries team cut the ribbon to start the Boston VisionWalk.

RESEARCH HIGHLIGHTS

Kiora Reports Vision Restoration in Phase 1/2 Clinical Trial for Photoswitch Therapy

Kiora Pharmaceuticals has announced some vision restoration for participants in ABACUS-1, its Phase 1/2 clinical trial in Australia for KIO-301, a molecule designed to bestow light sensitivity to retinal ganglion cells in people with advanced retinitis pigmentosa (RP) and other retinal diseases.

KIO-301 was initially tested in six people who have lost all or most of their photoreceptors, the retinal cells that make vision possible, to an advanced retinal disease. Known as a photoswitch, the molecule enables retinal ganglion cells to respond to light, thereby working like a back-up system for lost photoreceptors. Retinal ganglion cells, which are downstream from photoreceptors, often survive in advanced retinal disease but don't naturally respond to light. KIO-301 is delivered by a standard injection into the vitreous, the soft gel in the middle of the eye. One administration of the therapy appears to be effective for about a month.

The six patients in ABACUS-1 were split into two groups of three. Cohort 1 patients had no light perception or bare light perception. Cohort 2 patients had enough vision to see hand motion or count fingers. Three doses of KIO-301 were evaluated.

Cohort 1 patients appeared to have improvements in their ability to perceive the direction of movement and/or location of a window or lighted exit.

Cohort 2 patients had improvements in visual fields (peripheral vision) as measured by a Goldmann perimeter. Cohort 2 patients receiving the high dose had improvements in visual acuity, as measured by a Berkeley Rudimentary Vision Test, a test designed to evaluate vision in people without enough vision to read any letters on a typical eye chart.

New Report: Vitamin A Supplementation Provides No Vision Benefit to RP Patients

A Mass Eye and Ear research team led by Eric Pierce, MD, PhD, director of the Ocular Genomics Institute, and Jason Comander, MD, PhD, director of the Inherited Retinal Disorders Service, has determined that a high-dose vitamin A supplementation regimen does not slow vision loss in people with retinitis pigmentosa (RP). The new findings are from an analysis of additional data from the original 600-plus patient clinical trial at Mass Eye and Ear conducted by the late Eliot Berson, MD, between 1984 and 1991. Dr. Berson was the original director of the Berman-Gund Lab, the first research lab focused on inherited retinal diseases (IRDs) and the first lab funded by the Foundation.

Dr. Berson had reported that vitamin A supplementation modestly slowed loss of vision in people with RP. He also found that vitamin E supplementation accelerated vision loss. In the original vitamin A clinical trial, Dr. Berson measured patients' vision over time using the electroretinogram (ERG), which measures the retina's electrical response to light.

While Dr. Pierce and his team found no overall benefit from vitamin A in the new analysis, their findings reaffirmed that people with RP should avoid vitamin E supplementation because of its negative effect on retinal health.

The Foundation Fighting Blindness provided funding for both the original and follow-up studies on vitamins A and E.

Researchers believe that vitamin A supplements might be harmful for people with Stargardt disease and related cone-rod dystrophies, but these patients can eat a normal diet.

Patients should always consult with their physicians about changing any treatment or supplementation regimen. Dr. Comander said that RP patients who have been on vitamin A supplements for many years and feel they are doing well can continue the regimen under continued supervision of their doctor. Yearly liver function tests for patients taking the vitamin A supplementation regimen should be conducted.

BEACON STORY

The Future Holds Promise

Esther E. Biswas-Fiss, PhD, MB(ASCP) CM, is not only a first-generation college graduate but also the first in her family to finish high school. When she first started her undergraduate studies at the University of Washington, she did not have a single female professor. The first time Dr. Biswas-Fiss finally encountered a woman in science was when she started her PhD program.

"Throughout my graduate and postdoctoral studies, I have met a lot of very powerful, strong, excellent women scientists that have made wonderful discoveries," notes Dr. Biswas-Fiss. "There's a wonderful opportunity for women in the field of vision research."

Dr. Biswas-Fiss started her work as a chemist about 25 years ago and gravitated toward biomedical research. However, after attending an Association for Research in Vision and Ophthalmology (ARVO) conference, she became interested in using her skills as a biochemist to contribute to vision research.

"The vision research field is unique in that we have a great understanding and communication between scientists and clinicians, and we know a lot about genetics and biochemistry," says Dr. Biswas-Fiss. "We're really poised in the area of vision to implement those translational therapies like gene augmentation therapy, CRISPR, stem cell therapy, and biologics. The eye is really unique as an atomical organ to be receptive to those kinds of therapies that are maybe more challenging for diseases like cancer, diabetes, or cardiovascular disease."

Today, Dr. Biswas-Fiss is the Professor and Chair of the Department of Medical and Molecular Sciences, Director of Graduate Programs in Medical Sciences, and Director of Programs in Applied Molecular Biology and Biotechnology at the University of Delaware, College of Health Sciences.

The Foundation Fighting Blindness awarded her an Individual Investigator Research Award in June 2023, which is designed to concentrate research in areas with the greatest potential to move toward treatments and cures for inherited orphan retinal degenerative diseases and dry age-related macular degeneration.

Headshot of Dr. Esther Biswas-Fiss posing in her lab.

"We are so grateful to the Foundation Fighting Blindness for their generosity and for supporting our research," says Dr. Biswas-Fiss. "It is seen as a very prestigious award, so it isn't just about the money, which of course is important and allows us to continue our work, but it's also that this eminent group of scientists has given me the 'Good Housekeeping' seal of approval."

Her work being funded by the Foundation is titled, "Deciphering the Impact of ABCA4 Genetic Variants of Unknown Significance in Inherited Retinal Disease Prognosis." Dr. Biswas-Fiss is using computational modeling and experiments to determine whether ABCA4 variants of unknown significance (VUSs) lead to ABCA4-related disease. Solving these VUSs cases are critical to meet inclusion criteria in a clinical trial for ABCA4 therapies.

"Our task in the laboratory is to use computational techniques, so using computer modeling and in silico techniques, in combination with biochemical approaches, to try to make sense of these variants of unknown significance," says Dr. Biswas-Fiss. "We create proteins using recombinant DNA technology that harbors the same mutations that we see in the patients with the same genetic variants, and then we study how those behave biochemically relative to the normal or wild type protein."

Dr. Biswas-Fiss explains that today, the ABCA4 gene has over 3,000 genetic variants that have been identified in individuals when 25 years ago, there were only 200 variants identified. Of those, 1,500 are associated with the building blocks that make up the ABCA4 protein, meaning they could potentially affect the function of the protein and lead to disease.

"About 60% of those 1,500 are variants of unknown significance, and those patients are ineligible to be enrolled in clinical trials because they really have to know what the significance is of those variants," explains Dr. Biswas-Fiss. "And that's where our laboratory comes in and is hoping to make a difference."

Dr. Biswas-Fiss also notes that the importance of genetic testing has also really come to light in recent years and that her team is helping to fill in that roadmap from learning about genetic information to then getting treatment.

"10 to 15 years ago, it was difficult for patients to access genetic testing because many times their insurance would not cover it because it wasn't necessarily actionable," Dr. Biswas-Fiss recalls. "Thanks in part to the Foundation Fighting Blindness, funds have become available so patients whose insurance won't pay for the genetic testing can have it done now, which has really changed and is so important."

Dr. Biswas-Fiss is now guiding the next generation of scientists to make an impact in the field. One of her students has been studying with her for the last nine years. She's even leading the charge globally, as one of her students is from Turkey.

Dr. Biswas-Fiss' student Jazz Jones working in the lab.

"It's a very, very exciting time to be in science, and now I'm able to tell my students that in your lifetime, you'll be able to see the fruit of your labor," says Dr. Biswas-Fiss. "When I started out 25 years ago, I couldn't imagine that we would be in the position we are in today. As a researcher, what's difficult is that there isn't instant gratification; sometimes, the road is long and hard. But we've really gotten to a point in our research now where we can make a difference. It's all these little pieces of science put together, not just from our lab but from other labs, too, that is going to lead to those long-term gains that we see for patients. The future holds promise for individuals affected with inherited retinal diseases."

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IN FOCUS

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