

ALPHA-1-TO-ONE

Practical advice, personal experiences and

pertinent news for people touched by ALPHA-1



INNOVATION

INVESTMENT

INSIGHT

IMPACT

ALPHA-1
FOUNDATION

30th

1995
2025

Letter from Leadership



Momentum from the incredibly successful Alpha-1 Foundation (A1F) National Conference has launched us into fall. Our 30th anniversary recognition continues, highlighted in all A1F initiatives and events. This milestone commemorates and honors the legacy of those who have impacted the Alpha-1 community, especially Alphas and their families who A1F serves.

Like our current federal research funding environment, 30-years ago, the NHLBI Alpha-1 seven-year longitudinal study ended due to lack of resources. Unacceptable to our founders, John W. Walsh, Susan Stanley, and Sandy Lindsey, A1F was born. Walsh enlisted world-renowned experts to serve on the first Board of Directors, advisory committees, and to chair scientific workshops and conferences. With the help of knowledgeable physicians and researchers, A1F set out to invest in research and improved solutions for patients.

Today, 30 years later, thanks to our founders' insight, many of those same key stakeholders are still part of leadership and we are on the cusp of exciting and potentially transformative breakthroughs because of A1F's passion, commitment, and dedication to finding a cure.

ALPHA-1-TO-ONE

Practical advice, personal experiences, and pertinent news for people touched by Alpha-1, their families, and friends.

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**3300 Ponce de Leon Blvd.,
Coral Gables, FL 33134
(877) 2 CURE AI (228-7321)
alpha1.org**

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Collectively, we are a strong community. AIF continues to serve as the primary broker between industry partners, scientists, policy makers, clinicians, and nurses, alongside patients and their families. For three decades, AIF has designed and launched innovative, patient-focused programs and services supporting Alphas along their journey. We have created a solid infrastructure to promote pioneering scientific research and the establishment of collaborative partnerships to advance the development of novel therapies.

On this 30th anniversary, AIF shares a vision framed by four powerful pillars that define its work: Insight, Innovation, Investment and Impact. These pillars, woven into all our programming and messaging for 2025, continue to define who we are and what we do.

We were excited to launch AlphaDetect at the 2025 AIF National Conference. This centralized detection approach represents a new shift in focus, involving connecting, engaging and unifying the Alpha-1 community, ensuring access to informed providers, supporting the patient journey and bridging the evolving treatment landscape. Considering 90% of patients with Alpha-1 have no idea they're an Alpha,

AlphaDetect represents our commitment to finding and diagnosing all Alphas earlier and prioritizing providing them with answers, resources, and access to care. Early detection is vital for patients and their at-risk family members. It is the key to better outcomes, offering the possibility of timely interventions, effective treatments, a better quality of life, and ultimately saving lives.

Lastly, November is Alpha-1 Awareness Month. Now more than ever, we encourage you to participate by raising awareness and funds towards our mission (see page 20). Join AIF Virtual Walk 2025 and show your support for Alphas by joining a team or forming your own. Let's celebrate the 30-year milestone together—one step at a time!

Sincerely,



Scott Santarella
President & CEO
Alpha-1 Foundation

Contributing Editors

Genesis Corado; Cathey Henderson; Angela McBride; Shakira Molet; Miriam O'Day; Alexis Artiles Ojeda; Randel Plant; Linda Rodriguez; Scott Santarella

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Letters to the Editor: Please send letters to the editor to Jeanne Kushner, Senior Director of Communications & Policy at jkushner@alpha1.org



AIF is committed to finding a cure for Alpha-1 (Alpha-1) and to improving the lives of people affected by Alpha-1 worldwide.

*Diagnosed with Alpha-1.
+Diagnosed family member.



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Alpha-1 Foundation



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The 2025 Alpha-1 Foundation National Conference: 30 Years of Insight, Innovation, Investment, and Impact



The Alpha-1 Foundation (A1F) hosted the 2025 A1F National Conference from June 6th through June 8th in Miami, Florida, marking a significant milestone: A1F's 30th Anniversary. This year's event was not only a celebration of three decades of progress but also a tribute to the individuals and families whose courage, strength, and dedication continue to shape the Alpha-1 community. Under the theme inspired by four powerful pillars: Insight, Innovation, Investment, and Impact, this year's conference looked back on A1F's legacy while casting a bold vision for the future. These guiding principles were woven throughout the weekend's programming and will continue to frame A1F's work in the years ahead.

A1F held the Alpha Angels Memorial Service on Thursday, June 5th prior to the conference kickoff, a moving tribute honoring those we've lost in the Alpha-1 community with a special tribute to Fred Walsh, beloved Alpha, Friend and Advocate for the Alpha-1 Community. Fred's belief in patient empowerment resonated deeply; he championed the idea that individuals must take an active role in their health and advocate for themselves. His legacy will undoubtedly inspire future generations of Alphas to connect, support, and strive for a brighter future.

Over the next three days, nearly 500 in-person attendees and over 350 virtual attendees gained valuable insights from leading Alpha-1 experts, engaged in advocacy and educational sessions, and formed lasting bonds with fellow Alphas and caregivers. The conference kicked off Friday morning with a special welcome from Scott Santarella, President & CEO, who reflected on A1F's journey since 1995 and acknowledged the collective efforts of researchers, advocates, families, and donors who have fueled its mission.

The first full day featured engaging sessions, including the popular Alpha Empowerment Hour, where a panel of patients, parents, and advocates: Chelsea Boring, Craig and Melanie Hamilton, D.C. Young, and Nora Kemmerer shared their personal stories. Their journeys brought the themes of the conference to life, demonstrating how individuals can create meaningful change through awareness, education, and action. Other highlights included a presentation on the Alpha-1 Research Registry and Therapeutic Development Network (TDN), led by Alison Keaveny, Nadine Nuchovich, and Alicia Sable-Hunt, and Platinum Sponsor Presentations by AlphaNet, CSL Behring, Takeda, and Grifols. The day culminated in a festive dinner reception featuring Miami-inspired cuisine and interactive entertainment, including a live game show and improv comedy starring members of the Alpha-1 community.

Day Two spotlighted research and the future of Alpha-1 treatment. A1F Scientific Director Dr. Andrew Wilson presented the Alpha-1 research agenda, followed by a distinguished research panel with experts like Dr. M. Bradley Drummond, Dr. Virginia Clark, Dr. Monica Goldklang, and others discussing breakthroughs and ongoing studies. A crowd favorite each year, the Emerging Therapies in Alpha-1 session featured presentations from leading sponsors Beam Therapeutics, BioMarin Pharmaceuticals, Sanofi, Takeda, and Wave Life Sciences. Each shared their cutting-edge approaches to treatment, from base editing to RNA therapies, followed by an engaging Q&A with the audience.

Breakout tracks throughout the afternoon covered a wide range of topics, including Alpha-1 Liver Care, Family Testing and Clinical Trials, and Lung Health for Alpha-1 Kids, which offered attendees tailored insights into their condition. The evening wrapped with the highly anticipated 30th Anniversary High School Prom themed dinner and entertainment. Attendees dressed in their best prom attire to celebrate 30 years of progress with fun giveaways, a photo booth with printable pictures, and a lively community atmosphere.

The final day of the conference featured the Ice Cream for Alpha-1 Brunch, a sweet sendoff for attendees. This casual, festive event offered a chance to connect one last time while enjoying delicious ice cream treats and sneak peeks into next year's plans. A1F ensured that both in-person and virtual attendees had access to the full range of programming through a dynamic hybrid format. All main sessions were live-streamed, with on-demand access available throughout the weekend. Visit alpha1.org to access the video library and watch full conference sessions.

The 2025 A1F National Conference was a powerful reminder of what's possible when a community comes together with purpose and passion. As A1F celebrates 30 years of progress, the message is clear: with insight, innovation, investment, and impact, we are closer than ever to a cure for Alpha-1.

A1F extends its deepest gratitude to the 2025 sponsors whose commitment and support make this conference and year-round educational programming possible.

- Platinum Sponsors: AlphaNet, CSL, Grifols, Takeda
- Gold Sponsor: Accredo by Evernorth
- Emerging Therapies Sponsors: Beam Therapeutics, BioMarin Pharmaceuticals, Sanofi, Takeda, and Wave Life Sciences 📌

7th Global Research Conference and 10th Patient Congress Held in Lisbon, Portugal



The Alpha-1 Foundation (A1F) proudly held a powerful two-day event in Lisbon, Portugal marking the 7th Global Research Conference and 10th Patient Congress, uniting stakeholders from over 25 countries in the ongoing mission to cure Alpha-1 and enhance the lives of patients worldwide.

This year's gathering held special significance, as it also commemorated A1F's 30th anniversary. From its inception, A1F has built an international network of scientists, clinicians, and patient leaders dedicated to accelerating the path to a cure.

The 7th Global Research Conference, held on April 4th, convened a multidisciplinary group of experts for a deep dive into emerging science. The agenda was organized into two focused sessions "The Liver and The Lung" featuring presentations on topics ranging from cancer risk and liver disease progression in Alpha-1 to cutting-edge tools such as spatial single-cell proteomics and inflammasome activation. The sessions were designed to spark new ideas, encourage collaboration, and fast track promising treatments.

Meanwhile, the 10th Patient Congress, on April 5th, focused on education, empowerment, and

engagement. The day featured updates on emerging therapies from industry leaders including Beam Therapeutics, Kamada, Sanofi, Takeda, and Wave Life Sciences, alongside personal stories and global policy journeys that spotlighted the strength of the Alpha-1 community. Highlights included expert research panels, real-world perspectives from South America and Canada, and a deeply moving "Living with Alpha-1" patient panel.



This event reflects the heart of our mission. We're proud to offer a space where science meets patient voice, and where ideas can spark the next major breakthrough.

—Scott Santarella,
A1F President & CEO



Throughout the event, attendees, from researchers to patients to caregivers, were encouraged to create connections and exchange knowledge. AIF's Global Program continues to expand awareness, testing, and equitable access to care for Alphas worldwide.

Recordings are available in our Video Library at alpha1.org for those who were unable to attend or wish to revisit key moments from the Conference and Congress.

Thank you to the generous sponsors who make this event possible: AlphaNet, CSL, Grifols, Takeda, and the Emerging Therapy Sponsors: Beam Therapeutics, Kamada, Sanofi, Takeda, and Wave Life Sciences.

As AIF celebrates 30 years of progress, this event signaled a future filled with promise driven by global unity, scientific excellence, and the unwavering commitment to find a cure for Alpha-1. 



Alpha-1 Foundation Launches AlphaDetect, an Innovative New Model for Centralized Detection



AlphaDetect Board and Leadership Team

The Alpha-1 Foundation (A1F) is excited to announce the formation of AlphaDetect, a new non-profit subsidiary of A1F, to lead a centralized effort to identify individuals with Alpha-1 Antitrypsin Deficiency (Alpha-1 or AATD).

Alpha-1 is a genetically inherited condition that significantly increases the risk of developing pulmonary emphysema in adults and/or liver disease in both children and adults. Despite decades of research, and the development of numerous clinical testing guidelines, over 90% of individuals with Alpha-1 remain undiagnosed. Research continues to underscore the dangers of delayed diagnosis, including irreversible damage to the lungs and liver, and adverse impacts on survival.

“Although past detection efforts have made progress, they have not meaningfully changed the trajectory of Alpha-1 detection. The stubbornly persistent under-detection of Alpha-1 over the past 30 years underscores the urgent need for a more effective and sustainable approach.”

—James Stoller, MD, MS
A1F Board Member

AlphaDetect, powered by A1F, will lead a transformative initiative that unifies community stakeholders including patients, healthcare providers, advocates, and industry partners, all with a collective common purpose: to ensure no Alpha-1 patient is left undetected. After years of questions, receiving a diagnosis is the first step in an Alpha-1 patient's journey. Detection accelerates answers and informs decisions. Jon Hagstrom, A1F's Board Chair, reflects on his own personal story.



As an Alpha-1 patient, having a cure at the time I was diagnosed would not have changed my outcome. I still would have only had 29% lung function and been unable to walk up a flight of stairs. The most underserved Alphas are the ones who don't know they have the disease.

—Jon Hagstrom,
A1F Board Chair



AlphaDetect's focus is to standardize and integrate Alpha-1 screening into lung and liver care, as well as empower patients to find their own answers. AlphaDetect will offer free genetic testing for AATD, performed in a proprietary AlphaDetect laboratory, at no cost to patients or insurance.

AlphaDetect will have an on-site, dedicated, confidential customer care team to answer provider and/or patient inquiries regarding testing, test kit status, and results. A physician with expertise in AATD will also be on call to address clinical or scientific questions from testing healthcare providers. To evolve detection innovation for both lung and liver, an incubator space will be available for mission-aligned Alpha-1 research and detection-related innovation pilots.

ALPHA DETECT

Accelerating answers.
Informing decisions.



A more uniform and consistent approach is essential, and I'm thrilled to see the Alpha-1 community uniting around centralized detection. Only through collaboration and innovation can we achieve the breakthrough in early detection that's been needed for far too long.

—Mark Brantly, MD
Alpha-1 Specialist



AlphaDetect will be led by an experienced, dedicated team with deep roots in rare disease, detection strategy and the Alpha-1 community:



Julie Murray, CEO, with 20+ years of U.S. and Global industry, strategy, and business development leadership, will translate rare disease experience and multi-disciplinary detection approaches into organizational

leadership for AlphaDetect. She will also closely align AlphaDetect with A1F's mission.

Danielle Holm, Sr. Director, Operations, with 15+ years in market research, data analysis and business operations, will focus on building partnerships, collaborations, and tools that create new avenues for detection and detection-related technologies.



Larry Hinson, National Director, Provider Engagement, with 20+ years in rare disease provider engagement, market development and commercial leadership, will build and lead the engagement team to advance educational programs which will accelerate our national detection strategy.



AlphaDetect will also benefit from the expert guidance of its Board of Directors, including:

- **James Stoller, MD, MS**, AlphaDetect Board Chair, Chairman of the Education Institute and Senior Associate Dean for Academic Affairs at the Cleveland Clinic
- **Scott Santarella**, A1F President & CEO and AlphaDetect Vice Chair
- **Mark Brantly, MD**, Emeritus Professor of Medicine, University of Florida
- **David Brenner, MD**, President & CEO Sanford Burnham Prebys Medical Discovery Institute
- **Sutton Faller, MBA**, Chief Administrative Officer & Board Secretary, Cairn Therapeutics, Inc.
- **Jon Hagstrom**, Chair, A1F Foundation Board of Directors
- **David Lomas, MD, PhD**, Professor of Medicine, University College of London
- **Gerald Mosely, PhD**, Founder & President, CP&P Development, LLC
- **Julie Murray**, CEO, AlphaDetect



Alphas are hidden in plain sight. You have our commitment to accelerate and strengthen Alpha-1 detection through a unified and transformative approach. Please continue to share your thoughts and ideas, we are stronger together. Each of us has a role in helping an Alpha find their answer and take their first step into this incredible community of support.

—Julie Murray, CEO
AlphaDetect



A1F is looking forward to engaging and connecting across the Alpha-1 Community, in collaboration with AlphaDetect, to continue to improve the lives of those affected by Alpha-1. A1F will continue to be based in Coral Gables, Florida; AlphaDetect will be based in Durham, NC. More updates to come. 



AIF recognizes 2025 Grant Award Recipients During ATS



On Monday, May 19th, 2025, AIF hosted its annual AIF Grants Award Reception at the San Francisco Museum of Modern Art. The annual American Thoracic Society International Conference provides the ideal forum to honor AIF founders' vision of investing in research and science, recognizing the most recent grant recipients, and celebrating the distribution of more than \$100 million in grant funding over three decades.

This year, AIF celebrates its 30th anniversary, a milestone that commemorates and honors the legacy of those who have impacted the Alpha-1 community, especially the Alphas and their families whom AIF serves. For three decades, with the insight of the Alpha-1 community, AIF has designed and launched innovative patient-focused programs and services supporting Alphas along their journey, including a solid infrastructure to promote pioneering scientific research and the establishment of collaborative partnerships to advance the development of novel therapies.

AIF was proud of all the excitement around Alpha-1 (Alpha-1) at this year's international conference, with over 40 sessions and thematic poster sessions. AIF has invested over \$100 million towards research at over 130 institutions around the world, being the largest private funding source for Alpha-1. It is because of the brilliance in the Alpha-1 research community that the needle towards a cure continues to move forward. A cure that will ultimately change lives.



This annual gathering allows AIF to pause and reflect on the accomplishments that have been made in the field and to recognize those who will continue to advance research and bring us closer to a cure. We need more new, young investigators in the Alpha-1 research community to ensure that we continue to benefit from new ideas and high-quality research for years to come. We have a mission that cannot be achieved without the dedication of the scientific community.

—**Scott Santarella,**
AIF President & CEO



This April, the Grants Advisory Committee (GAC) awarded 21 in-cycle grants to well-deserving applicants totaling over \$3.75 million. AIF's research portfolio maintains a balanced focus between lung and liver studies, with 64% of projects dedicated to lung research and 36% to liver research. Thank you to the GAC members for their commitment and dedication: Dr. Andrew Wilson, AIF Scientific Director, Dr. Nicola Brunetti-Pierri (Chair), Dr. Jeffrey Atkinson, Dr. Igor Barjaktarevic, Dr. Maria Basil, Dr. Tomas Carroll, Dr. Dawn DeMeo, Dr. Iliaria Ferrarotti, Dr. Monica Goldklang, Dr. Joseph Kaserman, Dr. Ani Manichaikul, Dr. Stefan Marciniak, Dr. Victor Ortega, Dr. Pasquale Piccolo, Dr. Sheikh Tamir Rashid, Dr. Emer Reeves, Dr. Philip Rosenthal, Dr. Ron Rubenstein, Dr. David Rudnick, Dr. Karina Serban, Dr. Charlie Strange, Dr. Pavel Strnad, Dr. Alice Turner, Dr. Mike Wells, Dr. Darlene Dartt, Dr. Jesse Dill, and Jon Hagstrom, AIF BoD Chair.



We are at a particularly exciting and critical moment for the Alpha-1 community. There are now numerous new potential therapeutics in the pipeline with diverse mechanisms of action, and I am optimistic that one or more of these treatments will prove beneficial in upcoming clinical trials. AIF is working thoughtfully and with urgency on many fronts to realize this vision. At the same time, the importance of discoveries remains high. Funding scientific research is one critical part of this approach. Many researchers who have focused their careers on Alpha-1 research, myself included, might not be doing so if it were not for the support they have received from AIF over the years.

—Dr. Andrew Wilson, MD
AIF Scientific Director



Thank you to the event sponsors AlphaNet, CSL, Grifols, and Takeda.

Applications to the 2025 – 2026 In-Cycle Grants Award Program are now being accepted at <https://alpha1.org/grant-opportunities/>

The following recipients were recognized at the event:

Research Grants:

- Lisa Cabrita, PhD, University College London
- Paul Ellis, MBChB, PhD, University of Birmingham, UK
- Craig Hersh, MD, MPH, Brigham and Women’s Hospital
- Nilsson Holguin, PhD, Icahn School of Medicine at Mount Sinai
- Lela Lackey, PhD, Clemson University
- David LaFon, MD, University of Alabama at Birmingham
- Maurizio Molinari, PhD, Fondazione per l’Istituto di Ricerca in Biomedicina Bellinzona

- Emily Moser, PhD, University of Florida
- Nunzia Pastore, PhD, Fondazione Telethon ETS
- Pasquale Piccolo, PhD, Fondazione Telethon ETS
- Vickram Tejwani, The Cleveland Clinic
- Emily van’t Wout, MD, PhD, Leiden University Medical Center

Clinical Pilot Grant:

- Sandeep Bodduluri, PhD, University of Alabama at Birmingham

Pilot & Feasibility Grants:

- Emma Leacy, PhD, Royal College of Surgeons in Ireland
- Leandro Soria, PhD from Fondazione Telethon ETS

Postdoctoral Research Fellowship Grants:

- Debananda Gogoi, PhD, The Royal College of Surgeons in Ireland
- Shubham Kesarwani, PhD, Boston University
- Maria Magallon, PhD, University of Florida

John W. Walsh Career Development Grants:

- Shunqing Liang, PhD, University of Minnesota, Twin Cities
- Jingzhou Zhang, MD, MPH, Boston University

ATS/Alpha-1 Foundation Young Investigator Matching Grant:

- Shah Hussain, PhD, University of Alabama at Birmingham

Thank you again to the event sponsors AlphaNet, CSL, Grifols, and Takeda. 🇺🇸



The NonProfit Times recognizes the Alpha-1 Foundation



The Alpha-1 Foundation (A1F) was recently selected as the #2 overall of the **2025 Best Nonprofits to Work For** in the United States. In addition, A1F is ranked #1 in the Small Employer Category for organizations with 1 to 49 employees! The NonProfit Times, the leading national business publication for nonprofit managers, has partnered with Best Companies Group to identify nonprofit organizations where leaders have excelled in creating quality workplaces.

As A1F commemorates its 30th anniversary, this milestone celebrates and honors the legacy of those who have impacted the Alpha-1 community, especially the Alphas and their families who A1F serves. This impressive award applauds three decades of the staff's dedication to the Alpha-1 community. The longstanding commitment of this group of employees is evident in the combined number of years they have committed their careers to the mission.



We are excited and honored to have been selected and recognized as The NonProfit Times #2 Best Nonprofit to Work For and #1 in the small employer category. Our Board leadership, the tireless dedication of the staff, their commitment to the Alpha-1 patient community, and their belief in the mission of the organization are the key factors that contributed to this outstanding recognition. I am proud to work alongside this committed team of professionals each and every day.

—Scott Santarella
A1F President & CEO



This survey and awards program is designed to identify, recognize, and honor the best employers in the nonprofit industry, benefiting the industry's economy, workforce and businesses. The list is made up of 50 organizations.

To be considered for participation, organizations had to fulfill the following eligibility requirements:

- Must be in business a minimum of 1 year;
- Must be a nonprofit organization with 501 (c)(3) status;
- Have a facility in the United States;
- Have a minimum of 15 employees in the United States; and,
- An organization may enter as a group of nonprofits or as an individual organization as long as each participating organization is a separate legal entity (separate subsidiary). Branch offices may not enter separately from their parent nonprofit unless they are separate legal entities.

Nonprofits from across the United States entered the two-part survey process to determine Best Nonprofits to Work For. The first part consisted of evaluating each nominated organization's

workplace policies, practices, philosophy, systems, and demographics. This part of the process was worth approximately 25% of the total evaluation.

The second part consisted of an employee survey to measure the employee experience. This part of the process was worth approximately 75% of the total evaluation. The combined scores determined the top nonprofits and the final ranking. Best Companies Group managed the overall registration and survey process, analyzed the data, and determined the ranking.

For more information on The Nonprofit Times' Best Nonprofits to Work For program, visit www.BestNonprofitstoWorkFor.com.

Recognized for good operating practices, accountability, and responsible governance, AIF has received the National Health Council's Full Compliance Certification and the Charity Seal from the Better Business Bureau's Wise Giving Alliance. These are the highest accreditations attainable in the not-for-profit and voluntary health sectors. AIF has also received an Exceptional 4-Star rating by Charity Navigator, the highest rating given by that organization. GuideStar has also awarded the Platinum Seal of Transparency, their highest level of recognition, to AIF. 



SAVE THE DATE



**ALPHA-1
FOUNDATION**

**2026 AIF
NATIONAL
CONFERENCE**

JOIN US IN SAN DIEGO, CA!

JUNE 4-7, 2026

For more information, visit:
alpha1.org/national-conference/

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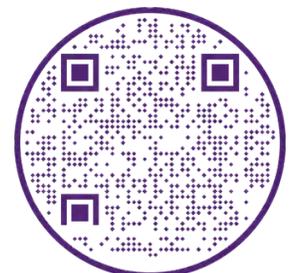


Alpha-1 Foundation Continuing Medical Education Series

The Alpha-1 Foundation (A1F) and the Cleveland Clinic are partners on a healthcare professional medical education series! Here are some highlights of the program. To take the course, visit: alpha1.org/continuing-medical-education-credits/

- This educational series is designed to aid in the knowledge, diagnostic, and treatment competence needs of healthcare providers to diagnose, treat, and provide better care for Alpha-1 patients.
- The professional education program targets various types of healthcare professionals, including pulmonologists, hepatologists, pediatric lung and liver physicians, liver and lung transplant physicians, nurse practitioners, physician assistants, genetics counselors, respiratory therapists, and internal medicine/general medicine physicians.
- Each video, as part of this series, includes a patient testimonial about their Alpha-1 experience.
- This online program has been approved for *AMA PRA Category 1 Credits™*
- A1F has partnered with Jamie Stoller, MD, and the Cleveland Clinic, which is accrediting the program to develop this new healthcare professional, medical education program.

Thank you to patients, Dr. Stoller and his Cleveland Clinic team, members of A1F's Medical and Scientific Advisory Committee, several board of directors members, and Cleveland Clinic clinical staff who volunteered to record videos to help us create a robust Alpha-1 Foundation Continuing Medical Education Series.





PROLASTIN®-C LIQUID fits my life.

—Heather, actual patient since 2018

**PROLASTIN-C LIQUID:
Trusted by patients and
their doctors for more
than 35 years.**



**PROLASTIN® C
LIQUID** alpha₁-proteinase
inhibitor (human)

- The #1 prescribed augmentation therapy for alpha₁-antitrypsin deficiency, or alpha-1*
- Proven to effectively raise the alpha₁ antitrypsin protein levels in patients with severe alpha-1
- The PROLASTIN DIRECT® program gives you the confidence of ongoing personalized support

Visit PROLASTIN.com to learn more.

*Data on file, Executive Summary, Grifols

IMPORTANT SAFETY INFORMATION

PROLASTIN®-C LIQUID is an alpha₁-proteinase inhibitor (human) (alpha₁-PI) indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of alpha₁-PI (alpha₁-antitrypsin deficiency).

Limitations of Use

- The effect of augmentation therapy with any alpha₁-PI, including PROLASTIN-C LIQUID, on pulmonary exacerbations and on the progression of emphysema in alpha₁-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials
- Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with PROLASTIN-C LIQUID are not available
- PROLASTIN-C LIQUID is not indicated as therapy or lung disease in patients in whom severe alpha₁-PI deficiency has not been established

PROLASTIN-C LIQUID is contraindicated in immunoglobulin A (IgA)-deficient patients with antibodies against IgA or patients with a history of anaphylaxis or other severe systemic reaction to alpha₁-PI products.

Hypersensitivity reactions, including anaphylaxis, may occur. Monitor vital signs and observe the patient carefully throughout the infusion. If hypersensitivity symptoms occur, promptly stop PROLASTIN-C LIQUID infusion and begin appropriate therapy.

Because PROLASTIN-C LIQUID is made from human plasma, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. This also applies to unknown or emerging viruses and other pathogens.

The most common adverse reactions during PROLASTIN-C LIQUID clinical trials in >5% of subjects were diarrhea and fatigue, each of which occurred in 2 subjects (6%).

Please see brief summary of the full Prescribing Information for PROLASTIN-C LIQUID on adjacent page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

GRIFOLS

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PROLASTIN[®]-C LIQUID

Alpha₁-Proteinase Inhibitor (Human)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PROLASTIN-C LIQUID safely and effectively. See full prescribing information for PROLASTIN-C LIQUID.

PROLASTIN-C LIQUID (Alpha₁-Proteinase Inhibitor [Human]) Solution for Intravenous Injection

Initial U.S. Approval: 1987

INDICATIONS AND USAGE

PROLASTIN[®]-C LIQUID is an Alpha₁-Proteinase Inhibitor (Human) (Alpha₁-PI) indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of Alpha₁-PI (alpha₁-antitrypsin deficiency).

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- The effect of augmentation therapy with any Alpha₁-PI, including PROLASTIN-C LIQUID, on pulmonary exacerbations and on the progression of emphysema in Alpha₁-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials.
- Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with PROLASTIN-C LIQUID are not available.
- PROLASTIN-C LIQUID is not indicated as therapy for lung disease in patients in whom severe Alpha₁-PI deficiency has not been established.

DOSAGE AND ADMINISTRATION

For intravenous use only.

- Dose: 60 mg/kg body weight intravenously once per week.
- Dose ranging studies using efficacy endpoints have not been performed with any Alpha₁-PI product, including PROLASTIN-C LIQUID.
- Administration: 0.08 mL/kg/min as determined by patient response and comfort.

DOSAGE FORMS AND STRENGTHS

For injection: approximately 500 mg (10 mL), 1,000 mg (20 mL) and 4,000 mg (80 mL) of a solution for injection in single-dose vials.

CONTRAINDICATIONS

- Immunoglobulin A (IgA) deficient patients with antibodies against IgA.
- History of anaphylaxis or other severe systemic reaction to Alpha₁-PI.

WARNINGS AND PRECAUTIONS

- Severe hypersensitivity and anaphylactic reactions may occur in IgA deficient patients with antibodies against IgA. Discontinue administration of the product and initiate appropriate emergency treatment if hypersensitivity reactions occur.
- Because PROLASTIN-C LIQUID is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

ADVERSE REACTIONS

The most common adverse reactions during PROLASTIN-C LIQUID clinical trials in > 5% of subjects were diarrhea and fatigue, each of which occurred in 2 subjects (6%).

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics LLC at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

GRIFOLS

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A1F Honors Kenneth Irvine at Bettina B. Irvine Gold Invitational

The Alpha-1 Foundation (A1F) annual Bettina B. Irvine Golf Invitational returned to Greenwich, Connecticut on May 28, 2025 raising vital funds and awareness. This year's event carried special meaning as A1F honored Kenneth Irvine, whose late wife Bettina founded the tournament in 2014.

Ken, an A1F board member, and his son Bill hosted the event at Greenwich Country Club, continuing the tradition Bettina began. Diagnosed with Alpha-1 in 1996, she turned her personal battle into advocacy, eventually serving as president of the Alpha-1 Association in 2002. "She really became a national spokesperson in treating and creating awareness for the disease," Ken recalled.

"We congratulate and honor Ken Irvine for his exemplary leadership on A1F's Board of Directors and Executive Committee and his longstanding commitment to the A1F mission. We are forever grateful to Ken for his tireless dedication to this annual event and to honoring the memory of Bettina through raising awareness and funds for Alpha-1. A special thank you to Bill Irvine, for his dedication to A1F throughout the year and at this very meaningful event," said Scott Santarella, A1F President & CEO.

Bill, involved since high school, sees the ripple effect of awareness. "Through social media, people reach out saying, 'My child has Alpha-1. My aunt was just diagnosed. Can you help?' And we've been able to point them to Alpha-1 specialists and local support groups. That's the kind of impact that really matters."



My mom was a public figure and would force herself to enter the uncomfortable while fighting a devastating disease. She had a double lung transplant and lived for 10 more years and survived the ICU two times. She defined what it was to be an Alpha, both as a patient and leader. The Alpha-1 community labeled her as the "Iron Lady".

—Bill Irvine



We shall all always remember Bettina as someone who spoke her mind and fought for what she thought was right. She was the voice of reason during challenging times.

—John W. Walsh
Founder of the
Alpha-1 Foundation



As research progresses, A1F remains grounded in its core mission: funding research towards a cure, patient support and education, advocacy, and awareness. As Bill emphasized, it's about "unconditional giving to make the biggest impact."

For Ken, it all comes back to Bettina's legacy. The annual invitational is more than just a day on the green—it's a living tribute to her vision, strength, and leadership. And for the Greenwich, Connecticut community, it's a chance to rally around a cause that continues to change lives.

Thank you to our **Special Event Sponsors:** AlphaNet, CSL, Grifols and Takeda. **Corporate Tournament Sponsors:** Citizens Bank, Linden Capital Advisors. **Individual Tournament Sponsors:** Cassie Richardson MacDonald, Cornelia Cogswell Rossi Foundation Inc., Hot Iron Health, Dr. Gordon & Ruth Cadwgan, The Irvine Family and The Marcott Family. 📌



NOVEMBER IS ALPHA-1 AWARENESS MONTH

Alpha-1 Awareness Month is a 30-day initiative that encourages the Alpha-1 community to share stories and resources and raise funds to support the search for a cure for Alpha-1 Antitrypsin Deficiency (Alpha-1).

This year's theme celebrates the Alpha-1 Foundation's (A1F) 30th anniversary. Honoring three decades of advancing research, raising awareness, and building a strong, supportive community of Alphas through Alpha-1 Support Groups, Alpha-1 specialists in Clinical Resource Centers (CRCs), legislators on Capitol Hill, and entire Alpha-1 community.



Whether you post on social media, fundraise for the A1F Virtual Walk 2025, or sign up for the Alpha-1 Research Registry, you are raising awareness for Alpha-1 and making an impact.

To learn more about Alpha-1 Awareness Month, visit: alpha1.org/alpha-1-awareness-month/



#ALPHA1AWARENESS



A1F VIRTUAL WALK 2025

#A1FVW25

This November, join the **A1F Virtual Walk 2025** and show your support for people impacted by Alpha-1 Antitrypsin Deficiency (Alpha-1). Whether you're walking for yourself, a loved one, a friend, or in memory of someone special, every step helps raise awareness and fund vital Alpha-1 research and related programs during **Alpha-1 Awareness Month**.



Pick any date, time, and place in November to participate in your neighborhood, at a local park, on your favorite trail, or even indoors. Get creative and set your personal goal! Whether it's a solo stroll or a team walk, it's all about getting out, moving, and making a difference.

Celebrating 30 Years of Impact

This year's walk is extra special as we celebrate the Alpha-1 Foundation's 30th Anniversary. That's three decades of advancing research, raising awareness, and building a strong, supportive community. Let's celebrate this milestone together—one step at a time.

As part of this year's walk, we're introducing a personalized button you can wear and share, highlighting who you walk for. Whether it's someone you love, someone you've lost, or the entire Alpha-1 community—let your walk tell your story.



Share Your Story

Post your A1F Virtual Walk photos and stories using #A1FVW25 and help inspire others to get involved. Your voice brings awareness, connection, and hope to the Alpha-1 community.

How to Participate:

- Register online: give.alpha1.org/A1FVirtualWalk25
- \$30 registration includes the official A1F Virtual Walk 2025 T-shirt
- Track your activity & fundraising efforts using the "Good Move" app
- Walk individually, join a team, or form a team—every step counts!

Let's move together—wherever you are—to honor, remember, and raise awareness for those impacted by Alpha-1. #A1FVW25 #Alpha1Awareness



For more info, contact Irene Calderon at icalderon@alpha1.org



Be the reason
progress never stops.

Be part of AIF's
MOMENTUM today!

Alpha-1 Foundation (AIF) Monthly Giving Program

By becoming a monthly donor, your gift will fuel critical advancements and provide hope to families affected by Alpha-1 Antitrypsin Deficiency (Alpha-1).

Why Give Monthly?

- **Sustained Impact**
Your support provides ongoing research and program funding.
- **Exclusive Updates**
Receive special behind-the-scenes progress reports and invitations to events.
- **Community Recognition**
Join a group of like-minded supporters who are making a difference.

As a **MOMENTUM** member, you'll receive:

- Recognition in the AIF Annual Report
- An exclusive **MOMENTUM** pin
- Invitations to special events
- Early access to AIF events

Your commitment, no matter the amount, ensures that together we can fight for better treatments, better outcomes, and a future free from Alpha-1.

Be part of a group of dedicated donors who contribute monthly to sustain groundbreaking research, patient support, and early diagnosis efforts.



Join the AIF Monthly Giving Program and help AIF build **MOMENTUM**. Visit alpha1.org/donate today!

For questions about monthly donations, please contact: donations@alpha1.org or call (877) 228-7321 ext. 275.



Building Friends for a Cure: Summer Highlights



This summer, the Ice Cream for Alpha-1 fundraising campaign proved that raising awareness can be just as joyful as it is impactful. Launched at the Alpha-1 Foundation (A1F) National Conference, the campaign inspired over 1,000 participants from around the country to host or attend ice cream fundraisers, engage local businesses, and celebrate the power of community. Together, these efforts surpassed the \$10,000 fundraising goal, supporting research, patient programs, and awareness for those living with Alpha-1.

From Omaha to Highland Park to New York City, and beyond, the Alpha-1 community came together in creative and heartfelt ways:

- **Nora Kemmerer & Chelsea Boring together with Big Red Alphas Support Group from Omaha, Nebraska** brought neighbors and local businesses together for the 2nd annual event filled with sweet treats and shared stories even coming out in the local media and raising over **\$2,500** dollars for Alpha-1.
- **Betsy Scher from Highland Park, Illinois**, founder of **Glow & Gather**, hosted a joyful gelato social that raised **\$2,110**.
- **Dr. Jeanine D'Armiento & the Columbia University Clinical Resource Center** hosted a

vibrant New York City event, with **Dr. Monica Goldklang, Peg Iverson**, Board of Director, **Sydney Harris**, co-support group leader joining to celebrate Alpha-1 community and clinical collaboration.

- **Melissa & Richie Ramirez** from Staten Island, NY hosted their own ice cream social before Richie appeared on live TV for **CBS Mornings** to share his journey from liver transplant recipient to young Alpha-1 advocate, alongside his heroic organ donor, Brian.

Across the country, **purple sprinkles, gelato scoops, and heartfelt conversations** turned into powerful events to raise awareness and funds for Alpha-1.

Ice Cream for Alpha-1 by the Numbers

- **1,000+** participants nationwide
- **\$10,000+** raised to support research and patient programs
- **Dozens of local businesses** opened their doors for sweet community gatherings
- **Events in 10+ states**, from living rooms to ice cream shops to A1F Clinical Resource Centers.

- **Countless scoops shared**, stories told, and awareness raised.

The **Ice Cream for Alpha-1** campaign showcased the creativity and dedication of the Alpha-1 community. Each scoop served, each conversation shared, and each story told brings us **closer to a future of hope, awareness, and continued progress.**

Cruising for a Cure: Erin Carr's Inspiring Boat-Bound Fundraiser

On May 2, 2025, the Alpha-1 community came together on the serene waters of **Lake Norman, North Carolina** for Cruising for a Cure—a heartfelt evening in support of **AIF's mission** to find a cure for Alpha-1.

Hosted by the Carr Family, the event was inspired by their personal journey after their young daughter, Tess, was diagnosed with Alpha-1 at just 9 months old. Surrounded by a compassionate and dedicated community, this event was a powerful reminder of the strength that can be found in unity, purpose, and shared hope.

A special thanks to **Erin Carr**, AIF board member, and her husband **John Carr** for their incredible leadership, generosity, and commitment to making this event such a meaningful success. Through their efforts, Cruising for a Cure raised an impressive **\$20,000** to support Alpha-1 research and programs—an amazing impact that will be felt by families across the country.

Guests enjoyed an evening cruise, heartfelt speeches, and inspiring conversations—all centered around the importance of Alpha-1 research and community support. As the sun set over Lake Norman, the spirit of hope was stronger than ever.

Thanks to everyone who joined the event, donated, and stood with the Carr family to make Cruising for

a Cure an evening to remember. Together, we are creating a brighter future for all Alphas.

2nd Annual Walk in Memory of Lorraine Cimino

On Sunday, May 18, 2025, more than **100 participants** gathered at the Red Devils Softball Field in Brooklyn, New York to honor the life and legacy of **Lorraine Cimino**—a woman remembered for her warmth, kindness, and the lasting impact she had on so many lives. The event raised an incredible **\$6,665 this year**, bringing the **two-year total to over \$14,000** in support of research and related programs of AIF.

The day was filled with heartfelt moments, beautiful weather, and meaningful connections. Guests enjoyed raffles—including a 50/50 and other fun prize drawings—while celebrating Lorraine's memory with friends, family, and community.

Thank you, **Mario** and **Santo Cimino**, for their tireless dedication and leadership in organizing this Building Friends for a Cure (BFC) fundraising and awareness event, and to those who attended, donated, or volunteered to make it a success.

Since 2005, the BFC program has become a cornerstone of Alpha-1 awareness and fundraising, touching lives across the country. These community fundraisers have not only raised funds for Alpha-1 research and programs but also educated and empowered participants with valuable Alpha-1 knowledge. BFC events are held virtually and in person, making it easy to fundraise for Alpha-1 and share a personal story. The program's influence extends beyond the patient community. By involving physicians, researchers, and industry partners, the BFC program offers a unique opportunity for stakeholders to gain firsthand insight into life with Alpha-1. 📌



GLASSIA

[Alpha₁-Proteinase Inhibitor (Human)]

For patients with emphysema caused by severe Alpha-1 antitrypsin deficiency.

No two alphas are alike. Neither are their needs.

GLASSIA® offers the most infusion setting options;
with your doctor, you can decide which works best for you.



AT HOME
SELF-INFUSION*



AT HOME
WITH NURSE



AT INFUSION
CENTER



AT CLINIC

*If self-infusion is deemed appropriate, ensure that you receive detailed instructions and adequate training on how to infuse at home or other appropriate setting and have demonstrated the ability to independently administer GLASSIA.



Scan the code or visit glassialiquid.com to learn about which infusion setting option may be right for you.



LINDA

Real GLASSIA patient
Avid traveler
Self-infuses at home

VANESSA

Real GLASSIA patient
Proud rodeo mom
Infuses at an infusion center



When you're prescribed GLASSIA, Takeda Patient Support is here for you.

What is GLASSIA?

GLASSIA is a medicine containing human Alpha₁-Proteinase Inhibitor (Alpha₁-PI) that is used to treat adults with lung disease (emphysema) because of severe Alpha₁-antitrypsin (Alpha₁) deficiency. GLASSIA is not meant to be used as a therapy for lung disease other than severe Alpha₁ deficiency. Effects of GLASSIA on worsening lung function and emphysema progression have not been proven in clinical trials. Long-term effects of Alpha₁ replacement and maintenance therapy have not been studied.

IMPORTANT SAFETY INFORMATION

What is the most important information I need to know about GLASSIA?

- GLASSIA can cause severe allergic reactions including hives, swelling in the mouth or throat, itching, tightness in the chest, trouble breathing, wheezing, faintness or low blood pressure
- If you will be taking GLASSIA outside a healthcare setting, ask your healthcare provider (HCP) about an epinephrine pen and/or other supportive care for certain severe allergic reactions.

Who should not use GLASSIA?

Do not use GLASSIA if you:

- Have immunoglobulin A (IgA) deficiency with antibodies to IgA
- Have a severe allergic reaction to human Alpha₁-PI products.

IMPORTANT SAFETY INFORMATION (continued)

What are the possible or reasonably likely side effects of GLASSIA?

If any of the following problems occur contact your healthcare provider (HCP) or call emergency services right away:

- Worsening or flare-up of your chronic obstructive pulmonary disease (COPD)
- Hives, swelling in the mouth or throat, itching, chest tightness, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.

The most common side effects that may occur are headache and upper respiratory tract infections.

Other possible side effects of GLASSIA include:

- Cough
- Sinus infection
- Chest discomfort
- Dizziness
- Increased liver enzymes
- Shortness of breath
- Nausea
- Fatigue

These are not all the possible side effects. Tell your HCP about any side effect that bothers you or that does not go away. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the Important Facts About GLASSIA on the next page.

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[Alpha₁-Proteinase Inhibitor (Human)]

Patient Information

GLASSIA®

(Alpha₁-Proteinase Inhibitor (Human)) Injection, For Intravenous Use

The following summarizes important information about GLASSIA (pronounced glass-see-ä). Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare professional, and it does not include all of the important information about GLASSIA. If you have any questions after reading this, ask your healthcare professional.

What is GLASSIA?

GLASSIA is a liquid medicine containing human Alpha₁-Proteinase Inhibitor (Alpha₁-PI) also known as alpha₁-antitrypsin (AAT), which is purified from human blood. The main purpose of infusing GLASSIA is to increase the levels of the AAT protein in your blood and lungs. AAT protein protects the lung tissue by blocking certain enzyme-caused damage. Such damage can lead to severe lung disease, such as emphysema.

Limitations of Use:

- The effects of increasing the AAT protein levels with GLASSIA or any other Alpha₁-PI product on worsening pulmonary function and progression of emphysema have not been proven in clinical trials.
- The long-term effects of AAT replacement and maintenance therapy with GLASSIA have not been studied.
- GLASSIA is not intended as a therapy in individuals with lung disease other than severe Alpha₁-PI deficiency.

Who should not take GLASSIA?

You should not use GLASSIA if you:

- Have immunoglobulin A (IgA) deficiency with antibodies to IgA
- Have had a severe allergic reaction to human Alpha₁-PI products

What is the most important information that I should know about GLASSIA?

Severe allergic reactions can occur with GLASSIA. Your doctor will inform you about signs of allergic reactions which include hives, swelling in the mouth or throat, itching, tightness in the chest, trouble breathing, wheezing, faintness, low blood pressure, or serious allergic reaction. If you have any of these reactions, discontinue use of the product and contact your physician and/or seek immediate emergency care, depending on the severity of the reaction.

If you or your caregiver will be administering GLASSIA outside a healthcare setting, ask your doctor about an epinephrine pen and/or other supportive care for certain severe allergic reactions. Ask your doctor to make sure you receive training on how and when to use any prescribed supportive care medicine and keep it close at hand when administering GLASSIA.

How should I take GLASSIA?

- GLASSIA is given directly into the bloodstream.
- You can get GLASSIA at your healthcare professional's office, clinic, hospital, or delivered directly to your home by a healthcare professional from a limited network of specialty pharmacy providers.
- Your healthcare professional will decide if self-infusion in your home is right for you. You should be trained on how to do infusions by your healthcare professional.

What should I tell my healthcare professional before I start using GLASSIA?

Before starting GLASSIA, tell your healthcare professional if you:

- Have IgA deficiency with antibodies to IgA.
- Have a history of severe allergic reactions to Alpha₁-PI products.

What are the possible or reasonably likely side effects of GLASSIA?

- A possible side effect to GLASSIA is worsening or flare-up of your chronic obstructive pulmonary disease (COPD) in which your breathing gets worse than usual.
- Call your healthcare professional or go to your emergency department right away if you get: Hives, swelling in the mouth or throat, itching, chest tightness, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- The most common side effects are headache and upper respiratory tract infections. Other possible side effects of GLASSIA include: cough, sinus infection, chest discomfort, dizziness, increased liver enzymes, shortness of breath, nausea, and fatigue.

These are not all of the possible side effects for GLASSIA. You can ask your healthcare professional for information that is provided to healthcare professionals. Talk to your healthcare professional about any side effects that bother you or that don't go away.

How do I store GLASSIA?

Store GLASSIA refrigerated or at room temperature.

- You can store GLASSIA in the refrigerator (36°F to 46°F [2°C to 8°C]). Do not freeze.
- You can store GLASSIA at room temperature (up to 77°F [25°C]) for up to one month. You must use GLASSIA within one month once you remove it from the refrigerator. Do not re-refrigerate GLASSIA once the product has been stored at room temperature.
- Keep the GLASSIA vial in the box until you are ready to administer the product.

Check the expiration date on the carton and vial label. Do not use GLASSIA after the expiration date.

Manufactured by:

Takeda Pharmaceuticals U.S.A., Inc.

Cambridge, MA 02142 USA

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Ask the Alpha Doc

During the 2025 Alpha-1 Foundation (A1F) National Conference in Miami, Florida, online participants submitted questions on the virtual environment (VE). While conference speakers answered many of the questions during the event, below are frequently asked questions that were received.



Q Can you explain the goals of the Alpha-1 Biomarkers Consortium (A1BC)?

A The Alpha-1 Biomarkers Consortium (A1BC) is a multi-site, prospective, observational cohort study of P1*ZZ Alpha-1. The project was designed to perform deep phenotyping of Alphas to understand links between molecular and genetic testing, pulmonary function testing, imaging, and clinical information to develop a picture of disease impact and progression in severe Alpha-1. At its heart, the A1BC was designed to understand factors involved with progression of emphysema as measured by lung density on computed tomography (CT) scans. The A1BC will help shed a light on disease heterogeneity (e.g., why two Alphas with a similar genetic background may have differences in disease risk), identify new therapeutic targets, and provide context of the 'natural history' of Alpha-1 over a 3+ year window of time. Additionally, the A1BC provides a framework for investigators to test hypotheses for topics like environmental factors or exacerbations that are not possible to do at a single site. The A1BC will be a vital resource for shaping our understanding of the complexities of severe Alpha-1.

Q What are some of the specific considerations that should be made for an adolescent or child to participate in research? Is the consent process different than that of an adult?

A Research involving participants under the age of 18 fits a legal definition of one of the "vulnerable" populations in research, and therefore involves a variety of additional protections, compared to studies in adults. Often, when possible, if a drug is being tested, some data that the drug is safe from studies in adults are required before trials in those under 18 can be started. Also, while the legal parent or guardian is required to give consent for research involving an under-age participant, the "assent" of the under-age participant is also required, depending on their age. This means that even if a teenager's legal guardian gives consent, if the teen participant themselves steadfastly refuses, then the research cannot proceed. As with any research, it is important for participants and their families to carefully evaluate the risks and benefits of participating in a study. The benefits might be to the individual and society. A full discussion of the study should include the child and the family, for the best and most informed decision.



**Brooks Thomas Kuhn,
MD, MAS**

UC Davis Health



Andrew Wilson, MD

Boston University
School of Medicine



What can ZZ Alphas be doing to help AIF with the research mission?



As AIF Scientific Director, can you explain the volume of research and interest in the field of Alpha-1 research and what this means for the Alpha-1 patient?



We are at a pivotal moment in Alpha-1 research. The field has never been more promising, with an unprecedented number of novel and potentially transformative interventions entering clinical trials. From gene therapies to innovative augmentation strategies, these breakthrough treatments could fundamentally change the trajectory of Alpha-1.



This is an exciting time in the research world for Alpha-1. Many technical advances that took place over the past 10-20 years have allowed the development of several classes of technologies being applied to test treatments for Alpha-1, all at the same time. These include gene therapy, gene editing, RNA editing, RNA interference, small molecules, and recombinant proteins. Several of these technologies are brand new and have only been tested in humans for a very short time.

However, this exciting progress creates a unique challenge: the considerable strain on our already limited population of Alpha-1 patients who are eligible and willing to participate in clinical research. With multiple competing studies, we risk overwhelming our community while potentially slowing the advancement of life-changing therapies.

Patients can support our research mission by staying engaged with AIF’s clinical trial networks, maintaining updated health records, and considering participation when appropriate studies become available. Equally important is spreading awareness within the Alpha-1 community about the importance of research participation and connecting newly diagnosed patients with research opportunities.

We can only move this research forward together. Your participation, advocacy, and commitment to advancing Alpha-1 science are essential to transforming these promising therapies into real-world treatments that will benefit current and future generations of Alpha-1 patients.

Fortunately for our community, Alpha-1 is one of the primary disease targets that companies are focused on with these emerging treatments. Why Alpha-1 instead of other diseases? This focus has occurred for a few major reasons. One of these is that Alpha-1 mostly results from a single, known mutation in the DNA (the “Z” mutation). A second reason has to do with the fact that the main organ that needs to be targeted with these new treatments is the liver—for a variety of reasons, liver targeting is easier compared to other organs. Finally, a third reason is the number of patients: Alpha-1 is a large, rare disease, so there are more patients to treat than is true for many other rare diseases. Taken together, there is a lot going on right now in the drug development space for Alpha-1! It is a lot to take in, but also an amazing opportunity for us as a community to find new treatments that will work for patients.



Q Why is it important for Alphas to be in the AIF Research Registry?

Q Are there any specific considerations that a patient should have when choosing to participate in one trial over another? What questions should patients be asking?

A The AIF Research Registry is a powerful tool for the Alpha-1 community in clinical research and patient advocacy. Thousands of patient participants have provided AIF with invaluable information about disease diagnosis, progression, and symptom burden. Furthermore, participation in the Alpha-1 Research Registry allows patients to stay involved and be the first to hear about clinical trials with targeted contact from AIF based on personal registry information.

A Choosing to participate in a clinical trial is a very personal decision. Research studies are performed to answer specific questions. Before joining a research study, patients should first ask about its purpose and objectives. Clinical trials for Alpha-1 test how well new treatments work, their safety, and the right dose and duration. Ask how long the trial lasts, if it affects future study participation, the chance of receiving a placebo, and any known risks. Since outcomes can't be predicted before the study is done, discussing trial participation with your Alpha-1 doctor is always recommended. 

Join the Alpha-1 Research Registry



We are recruiting for Alpha-1-related studies and need your participation!

We encourage you and your family members to join the Alpha-1 Research Registry to help advance Alpha-1 research, diagnosis, and treatment.

Anyone diagnosed with Alpha-1 can join the Registry in three steps:

1. Complete a Registration Form
2. Sign the Informed Consent
3. Complete the Questionnaire



To enroll or for more information:
alpha1.org/join-the-alpha-1-research-registry



Alphas Go to Washington, DC: Momentum Builds for Home Infusion and Oxygen Access



Early September, AIF advocates from across the country gathered in Washington, DC, for a Lobby Day bringing the Alpha-1 community's lived experience directly to Capitol Hill. Over two packed days, volunteer advocates met with more than 75 congressional offices to advance two priorities: permanent Medicare coverage of home infusion for Alpha-1 augmentation therapy and stronger access to supplemental oxygen, including liquid oxygen, for those who need it most.

Advocates urged support for H.R. 2343, the John W. Walsh Alpha-1 Home Infusion Act of 2025, which would make at-home augmentation therapy a permanent Medicare Part B benefit for eligible Alpha-1 beneficiaries. The bill is a priority in the 119th Congress and, as of September 25, 2025, has 30 cosponsors and bipartisan momentum in the House. Reps. María Elvira Salazar (R-FL) and Chellie Pingree (D-ME) reintroduced the John W. Walsh Alpha-1 Home Infusion Act in March 2025. The legislation would allow eligible Medicare beneficiaries

with Alpha-1 to receive their weekly augmentation infusions at home under qualified home infusion suppliers and clinical oversight paralleling coverage that many already experience under commercial plans, TRICARE, and Medicaid. Today, too many patients are forced to leave home for clinic or hospital infusions once they age into Medicare.



Access to home-based care reduces healthcare costs while giving people dignity and peace of mind as they receive quality care in their home. I am proud to lead this legislation, which would make life easier for Medicare patients struggling with this rare genetic disease.

—**María Elvira Salazar**
Representative



Named for our community's tireless champion John W. Walsh, H.R. 2343 ensures Medicare covers home infusions for Alpha-1 augmentation. Now is the time to ask your Representative to cosponsor. Take action with one click via AIF's advocacy platform: <https://mstr.app/15ab3afd-10c4-4ffd-8fc6-239cbbc7823e>

Advocates also pressed for H.R. 2902, the Supplemental Oxygen Access Reform (SOAR) Act of 2025, to improve access to oxygen. The bill increases payment for liquid oxygen and recognizes a home visit by a respiratory therapist as an essential part of patient education. The bill would remove oxygen from Medicare's competitive bidding program beginning January 1, 2026, update payment policy, and protect beneficiary choice and access. As of September 25, 2025, H.R. 2902 has 24 cosponsors and bipartisan support; a Senate companion (S. 1406) is led by Senators Bill Cassidy, Mark Warner, and Amy Klobuchar.



When Alphas sit across from lawmakers and staff, policy turns into people. Our stories cut through the noise, and this year, we saw offices move from listening to leaning in.

—Daniel Grimm,
Alpha-1 Foundation
Patient Advocate



On September 8, A1F, together with the Critical Path institute, co-hosted the CPA-1 workshop, “Shaping the Future of AATD: Patient Perspectives to Drive the Next Decade of Innovation.” Patients, caregivers, clinicians, researchers, industry, and regulators explored pathways to regulatory-accepted tools and endpoints to accelerate therapy development for Alpha-1. CPAI’s mission is to deliver actionable, regulator-ready solutions through a public-private partnership.

A1F remains steadfast: by pairing evidence-based policy with patient-powered advocacy, we are driving tangible changes in Medicare coverage and catalyzing innovation for our community.

Get involved: Join our advocacy network by contacting Jeanne Kushner, Senior Director of Communications & Policy, at jkushner@alpha1.org. 



Clinical Trials 101

You can help researchers discover and develop new treatments for Alpha-1!

Clinical trials are essential to advancing treatments and improving quality of life for people with Alpha-1. They follow strict phases to test safety and effectiveness, and offer participants the chance to contribute to research that could benefit future generations. Learn how trials work, what to expect, and how to get involved.

For more information, visit:

alpha1.org/clinical-trials-101



Send a Special E-Card with Your Donation

When you donate A1F, you can send an electronic card to celebrate a special occasion or honor a loved one.

Choose from a variety of occasions:

- **Birthdays:** Send birthday wishes with a heartfelt e-card.
- **Memorials:** Honor the memory of a loved one with a touching tribute.
- **And More:** E-cards for special moments and celebrations.

How It Works:

- Make a Donation at alpha1.org/donate
- Select the perfect e-card from our collection
- Add a personal message to make it truly special
- Enter the recipient's email, and we'll take care of the rest!

Every e-card sent helps support our mission, making your gesture even more meaningful.

Spread joy and make a difference today!



Helping Alphas reach for the stars for...

20 years and beyond!

"It is so important to advocate for yourself. You have to be strong and pursue what you need for treatment." — Dee, using ZEMAIRA for over 18 years



Call 1-866-ZEMAIRA (1-866-936-2472)
from 8AM to 8PM ET.



Dedicated case managers



Financial assistance programs



Personalized 1:1 insurance guidance



Tools to stay on track



Community support and encouragement

Learn more at [ZEMAIRA.com](https://www.ZEMAIRA.com)



Important Safety Information

ZEMAIRA[®], Alpha₁-Proteinase Inhibitor (Human), is indicated to raise the plasma level of alpha₁-proteinase inhibitor (A₁-PI) in patients with A₁-PI deficiency and related emphysema. The effect of this raised level on the frequency of pulmonary exacerbations and the progression of emphysema have not been established in clinical trials.

ZEMAIRA may not be suitable for everyone; for example, people with known hypersensitivity to components used to make ZEMAIRA, those with a history of anaphylaxis or severe systemic response to A₁-PI products, and those with certain IgA deficiencies. If you think any of these may apply to you, ask your doctor.

Early signs of hypersensitivity reactions to ZEMAIRA include hives, rash, tightness

of the chest, unusual breathing difficulty, wheezing, and feeling faint. Immediately discontinue use and consult with physician if such symptoms occur.

In clinical studies, the following adverse reactions were reported in at least 5% of subjects receiving ZEMAIRA: headache, sinusitis, upper respiratory infection, bronchitis, fatigue, increased cough, fever, injection-site bleeding, nasal symptoms, sore throat, and swelled blood vessels.

Because ZEMAIRA is made from human blood, the risk of transmitting infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

Please see full prescribing information for ZEMAIRA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

You can also report side effects to CSL Behring's Pharmacovigilance Department at 1-866-915-6958.



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1020 First Avenue, PO Box 61501
King of Prussia, PA 19406-0901 USA
www.CSLBehring.com www.ZEMAIRA.com
USA-ZMR-0269-JUN25

ZEMAIRA®, Alpha₁-Proteinase Inhibitor (Human)
lyophilized powder for reconstitution for intravenous use
Initial U.S. Approval: 2003

BRIEF SUMMARY OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ZEMAIRA safely and effectively. See full prescribing information for ZEMAIRA.

INDICATIONS AND USAGE

- ZEMAIRA is an alpha₁-proteinase inhibitor (A₁-PI) indicated for chronic augmentation and maintenance therapy in adults with A₁-PI deficiency and clinical evidence of emphysema.
- The effect of augmentation therapy with ZEMAIRA or any A₁-PI product on pulmonary exacerbations and on the progression of emphysema in A₁-PI deficiency has not been demonstrated in randomized, controlled clinical studies.
- ZEMAIRA is not indicated as therapy for lung disease patients in whom severe A₁-PI deficiency has not been established.

DOSAGE AND ADMINISTRATION

For intravenous use after reconstitution only.

- The recommended weekly dose of ZEMAIRA is 60 mg/kg body weight. Dose ranging studies using efficacy endpoints have not been performed with ZEMAIRA or any A₁-PI product.
- Administer through a suitable 5 micron infusion filter (not supplied) at room temperature within 3 hours after reconstitution.
- Do not mix with other medicinal products. Administer through a separate dedicated infusion line.
- Administer at a rate of approximately 0.08 mL/kg/min as determined by the response and comfort of the patient.
- Monitor closely the infusion rate and the patient's clinical state, including vital signs, throughout the infusion. Slow or stop the infusion if adverse reactions occur. If symptoms subside promptly, the infusion may be resumed at a lower rate that is comfortable for the patient.

DOSAGE FORMS AND STRENGTHS

ZEMAIRA is supplied in a single-dose vial containing approximately 1000 mg, 4000 mg, or 5000 mg of functionally active A₁-PI as a white to off-white lyophilized powder for reconstitution with 20 mL, 76 mL, or 95 mL of Sterile Water for Injection, USP. The amount of functional A₁-PI is printed on the vial label and carton.

CONTRAINDICATIONS

- History of anaphylaxis or severe systemic reactions to ZEMAIRA or A₁-PI protein.
- Immunoglobulin A (IgA)-deficient patients with antibodies against IgA, due to the risk of severe hypersensitivity.

WARNINGS AND PRECAUTIONS

- Observe any signs of hypersensitivity such as tachycardia, hypotension, confusion, syncope, oxygen consumption decrease, and pharyngeal edema when administering ZEMAIRA to patients with known hypersensitivity to an A₁-PI product.
- Patients with selective or severe IgA deficiency can develop antibodies to IgA and, therefore, have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. If anaphylactic or severe anaphylactoid reactions occur, discontinue the infusion immediately.
- Because ZEMAIRA is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

ADVERSE REACTIONS

- Serious adverse reactions reported following administration of ZEMAIRA in pre-licensure clinical trials included one event each in separate subjects of bronchitis and dyspnea, and one event each in a single subject of chest pain, cerebral ischemia and convulsion.
- The most common adverse reactions occurring in at least 5% of subjects receiving ZEMAIRA in all pre-licensure clinical trials were headache, sinusitis, upper respiratory infection, bronchitis, asthenia, cough increased, fever, injection site hemorrhage, rhinitis, sore throat, and vasodilation.

To report SUSPECTED ADVERSE REACTIONS, contact CSL Behring Pharmacovigilance at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/med-watch.

Based on January 2024 revision

Bringing Awareness to Alpha-1: a Little Boy's Big Journey

At just two years old, Richard "Richie" Ramirez was diagnosed with Alpha-1, a rare genetic condition that can cause serious lung and/or liver disease. For his parents, Melissa and Richard, the diagnosis was devastating. Their miracle baby, born after the couple's third and final round of IVF, suddenly faced a future clouded with uncertainty. By age four, Richie's liver was failing.

His only hope: a living donor.

That miracle arrived in 2020 in the form of Brian Flynn, a 51-year-old stranger who chose to give part of his liver to save Richie's life. The transplant was a success, and the bond that grew from that act of generosity has reshaped both families forever. Though Flynn originally chose to donate anonymously, fate had other plans. A social worker informed him that Richie's family was open to correspondence, and soon after, Melissa's heartfelt bedside letter found its way to him. Flynn admits he "sobbed" reading it, overwhelmed by the gratitude and hope it carried.



They all call me the GOAT [greatest of all time] for having shared part of my liver with him four years ago. But Richie's the true hero of this story. The best gift for me is seeing him thrive and bring so much joy to so many people. Donating was the most amazing thing I've done in my life.

—Brian Flynn



Their first meeting came a year later, and their relationship has only deepened since. Earlier this year, Flynn surprised Richie at his first communion in Brooklyn, NY. When Richie turned and saw him standing in the church, he burst into tears. The emotional reunion, witnessed by family, friends, and Flynn's wife Amy, was a vivid reminder of the lifelong impact of organ donation.



Richie hasn't let his diagnosis define him but instead, he's embraced it as a platform for advocacy. This summer, just weeks after attending A1F National Conference, he proudly hosted his own "Ice Cream for Alpha-1" fundraiser in Brooklyn, NY. Organized by his parents at Patrick O'Rourke Playground, the event was filled with laughter, love, and a strong sense of community. Friends, family, and supporters gathered to enjoy sweet treats, raffles, and games, ultimately raising more than \$2,100 for A1F.

The day was made even more meaningful by the presence of fellow Alpha families, like the Ciminos, and by the generosity of relatives near and far. "What sweet success!" Melissa reflected after the event. "Together, we scooped up smiles and support for a great cause. Thank you for making it unforgettable." Every dollar raised went directly to research and programs that bring us closer to a cure for Alpha-1, emphasizing the family's commitment to turning their personal journey into a mission for broader awareness and change.

But their advocacy doesn't stop with ice cream. Each year, the Ramirez family leads Team Lucky Luciano in A1F Virtual Walk, gathering loved ones in New York

and Florida to honor Richie's journey. Through A1F's Building Friends for a Cure program, their efforts have raised critical funds and awareness, helping to push forward research and provide resources for families impacted by Alpha-1.

Richie's story has now reached national audiences, with a feature on CBS Mornings shining a spotlight on the realities of Alpha-1 and the power of organ donation. His young voice, paired with Brian Flynn's generosity, embodies the message that one person's decision can transform a life. For the Ramirez family, every milestone, whether a communion, a conference, or a neighborhood fundraiser, is a chance to celebrate how far Richie has come and to inspire others to join the fight against Alpha-1.

"Proof that love is the strongest emotion, and showing up matters," Melissa wrote after Brian's surprise reunion with Richie. It's a truth their family lives every day. And thanks to one donor's gift, one little boy continues to thrive: bringing hope, awareness, and plenty of smiles, one scoop at a time. 

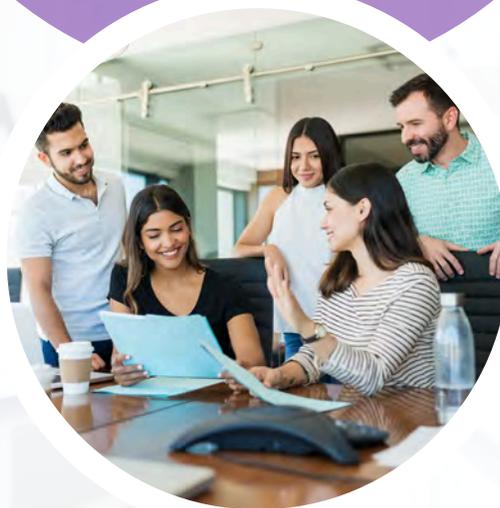


WORKPLACE GIVING TO A1F

PAYROLL DEDUCTION

United Way participants need only write "Alpha-1 Foundation" on the line for "other" designees on the payroll deduction form.

Combined Federal Campaign (CFC) participants (postal workers, court employees, and military, FBI, DEA, and IRS, for example) must specify our code 11717 to select the Alpha-1 Foundation.



MATCHING GIFTS

Hundreds of companies offer a matching gift program, which can double or, in some cases, triple your contribution to the Alpha-1 Foundation.

Contact your human resources department to find out if your company participates in a matching gift program.

Learn more: alpha1.org/workplace-giving/

For more information regarding workplace giving, please contact Linda Rodriguez at lrdriguez@alpha1.org or call (877) 228-7321, ext. 237



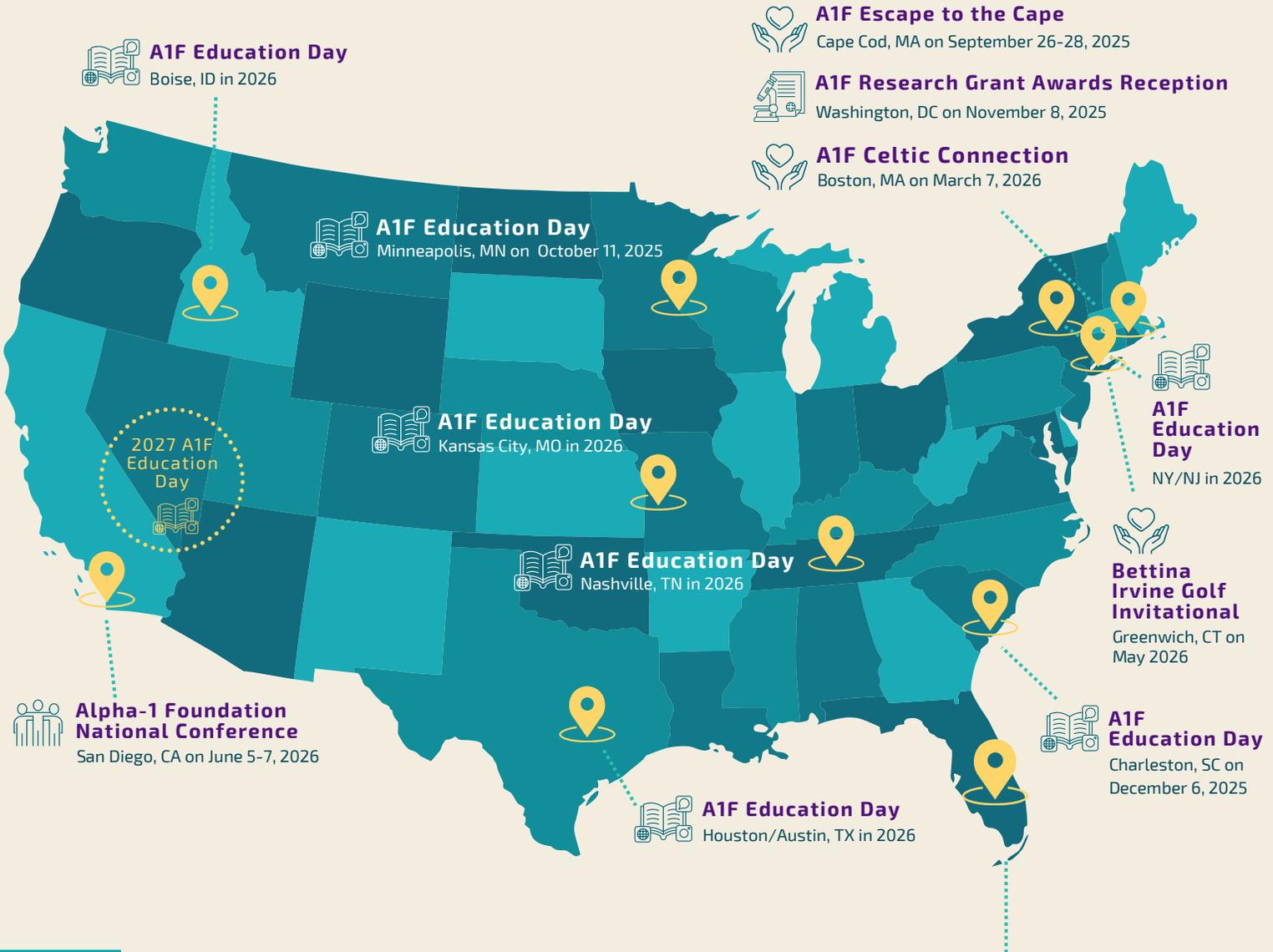
ARE YOU ON A JOURNEY WITH ALPHA-1 LIVER DISEASE?

The Redwood Study is looking for adults 18 to 75 years of age who have a confirmed or suspected diagnosis of Alpha-1 Liver Disease with PiZZ genotype. There is currently no approved treatment available for Alpha-1 Liver Disease. The investigational study drug aims to reduce the production of the abnormal Z-AAT protein and its buildup in the liver. To learn more and see if you may qualify, talk to your doctor and visit Alpha1.org/Redwood-Study-Prescreening today.



**The
Redwood
Study**

2025-2026 Major Meetings & Events



Virtual

VIRTUAL

The Virtual Alpha-1 Foundation Education Day & State of the Union will take place **January 28, 2026**.

Alpha-1 Global

England

The 28th Gordon L. Snider (GLS) Critical Issues Workshop will be held in London, UK on **October 3-4, 2025**.

Alpha-1 Gulf Coast Bike Ride
Dunedin, FL on October 18, 2025

29th Gordon L. Snider (GLS) Workshop
Miami, FL on April 17, 2026

A1F Research Grant Awards Reception
Orlando, FL on May 18, 2026

To learn more about all Alpha-1 Foundation events in 2025 and 2026, including virtual events and initiatives, visit: alpha1.org/calendar

Dates may be changed at the discretion of A1F.

Calendar of Events 2025-2026

Are you receiving our emails?

Do you receive the monthly e-newsletter "Community Currents"? This is a good time to check that you are on our e-mail list. Update your contact information by visiting alpha1.org.



For additional support group meetings, please check the calendar of events on alpha1.org/calendar

AIF Support Group Meetings

November 1, 2025
Alpha Opportunities
Oaks, PA

November 8, 2025
Glass City Alphas Walk
Toledo, OH

November 8, 2025
SF Bay Area Alphas
San Francisco, CA

November 9, 2025
Big Red Alphas Walk
Omaha, NE

December 13, 2025
Gainesville Alphas
Gainesville, FL

AIF Education Events

December 6, 2025
Charleston AIF Education Day
Charleston, SC

January 28, 2026
Virtual AIF Education Day &
State of the Union
Virtual Platform

June 4-7, 2026
AIF National Conference
San Diego, CA

AIF Upcoming Events

November 2025
AIF Virtual Walk 2025
Nationwide

March 7, 2026
AIF Celtic Connection
Boston, MA



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Be sure to update your e-mail address and contact information by visiting:

 alpha1.org/subscribe

