

PERSPECTIVE

A MAGAZINE FROM THE TSC ALLIANCE



2022 World TSC Conference in review

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TSC Alliance and Bhatia Family Foundation announce new research collaboration

PAGE 22



As we near the end of 2022, the TSC Alliance® remains committed to creating a future where each individual and family affected by tuberous sclerosis complex (TSC) has everything they need to live their fullest life. Nothing demonstrates this more than this past Summer's 2022 World TSC Conference in Dallas, TX!

It was truly amazing to finally bring the TSC community back together following the COVID pandemic. Our organization's and the TSC community's strength has always been creating a true sense of family as we work side by side on our mission to find a cure for TSC while improving the lives of the those affected. Continuously keeping each of your needs in mind – in everything we do – serves as the “true north” of the TSC Alliance.



Thorpe Richards

The 2022 World TSC Conference offered something for all participants. In particular, several sessions highlighted the ongoing and exciting advances in TSC research, including the TSC Alliance's own research platform and current clinical trials. You can read more about the 2022 World TSC Conference on page 8.

The TSC community's participation in research is, of course, crucial. On page 16, you can learn more about the TSC Alliance's Natural History Database, Biosample Repository and new Self-Report Portal. We are also deeply grateful to the Bhatia Family Foundation's extraordinary \$2.5 million gift to support research (see page 22).

While it truly is a remarkable time in the history of the TSC Alliance with so much recent progress, we do want to share our deepest sympathies to John and Jordan Richards on the recent and unexpected loss of their son Thorpe. Many of you know John from his dedicated years on the TSC Alliance Board of Directors, as a current member of our Corporate Advisory Board and as a very active participant in our Government Relations Committee. Jordan has been an outstanding advocate, volunteer and supporter of our organization for more than two decades.

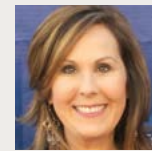
From Orin Warder's Homily for Thorpe: “To quote his father,

Message from leadership

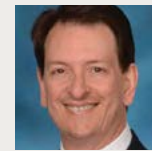
for someone who could not utter a word, he was particularly adept at getting whatever it was he wanted. And to quote both Jordan and John – all he really ever wanted was to love. Anyone who knew Thorpe could attest to that truth. John Thorpe Richards III was ALL love.”

We are dedicating this issue of *Perspective* in Thorpe's memory and on his behalf urge readers to consider registering for the Maryland Brain and Tissue Bank at tscalliance.org/brainandtissue. This is an issue very important to the family, and we want to honor them by sharing this important link.

Please remember no one is ever alone on his or her journey with tuberous sclerosis complex with the TSC Alliance.



Kari Luther Rosbeck
President & CEO



Peter B. Crino, MD, PhD
Chair, Board of Directors

PERSPECTIVE

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TSC Alliance®
8737 Colesville Road, Suite 400
Silver Spring, MD 20910 USA
(301) 562-9890 Toll-free: (800) 225-6872
Fax: (301) 562-9870
tscalliance.org | [@tscalliance](https://twitter.com/tscalliance)

KARI LUTHER ROSBECK
President and Chief Executive Officer

JAYE D. ISHAM
Senior Vice President,
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Managing Editor

If you have opinions, questions or articles for *Perspective*, we would like to hear from you. Please contact the managing editor to obtain a submissions form and guidelines.

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TSC Alliance Honors Dr. Michael and Janie Frost



During the 2022 World TSC Conference's Blue Night Dinner, the TSC Alliance presented a TSC Champion Award to Dr. Michael and Janie Frost. Michael and Janie have both devoted their careers and lives to helping individuals and their families affected by TSC.

"The impact of Dr. Michael and Janie Frost on the TSC community has been profound," said Kari Luther Rosbeck, President & CEO. "Their deep compassion and extraordinary commitment helped create an improved quality of life for tens of thousands of individuals and families."

Dr. Frost is a board-certified child neurologist and epileptologist. He was a founding team member of Minnesota Epilepsy Group in 1991 and established the Upper Midwest TSC Clinic Without Walls after meeting Dr. John Hulbert at a TSC Alliance research conference in 2002.

During his tenure as Co-Director of the TSC Clinic, he served as an investigator on several pivotal clinical trials including Afinitor, which led to its approval for treating SEGAs in 2010; Epidiolex that led to its approval in 2020; and the current PREVeNT Trial, the first preventative clinical trial for epilepsy in the United States. Additionally, Dr. Frost served on the Clinical Consensus Group in 1998 to help establish the original TSC Clinical Consensus Guidelines and continued this role through two additional revisions with a special expertise in comprehensive and coordinated care. Dr. Frost continues to provide his guidance as a member of the TSC Alliance Professional Advisory Board.

Janie Frost is a trained epilepsy nurse. She served as a member of the TSC Alliance Board of Directors from 2006-2011 and as Secretary in 2009. With her expertise in clinical care, she helped organize the 1999 (Washington, DC) and 2001 (San Diego) National Family Conferences and chaired the National and World TSC Conferences in 2006 (Chicago), 2014 (Washington, DC) and 2018 (Dallas). These conferences are among the most prolific gatherings of the global TSC community and were successful because of her outstanding leadership and dedication. Janie also generously served on the planning committee for the Minnesota-based Sound Bites events as well as the 35th, 40th and 45th TSC Alliance anniversary galas.

In addition, Michael and Janie recently established the Frost Clinical Research Legacy Fund at the TSC Alliance, a leadership gift for the Investment to Accelerate Research, providing funding to support the TSC Natural History Database and Biosample Repository.

Dr. Frost pioneered one of two original pilot sites of the Natural History Database in 2006

and has long been a proponent of clinical research to improve quality of life for those with TSC. The Frost Clinical Legacy Fund aims to broaden the diversity of biosamples through mobile blood collection and focused equity, diversity and inclusion initiatives; expand use of data and biosamples by funding a broader diversity of researchers; accelerate development of patient-centered outcome measures in clinical trials and facilitate preventative treatments; and drive analyses of data and biosamples and fund work to address hypotheses. The outcomes of their gift are to help in the collection of more biosamples, growing a registry of patient-reported outcomes and supporting whole genome sequencing in a portion of biosamples.

"Over the past 30 years, we have witnessed dramatic improvement in care and understanding of those who live with TSC," shared Dr. Frost. "The TSC Alliance research has also led to incredible improvement in quality of life. Our gift honors the commitment of the TSC Alliance to individuals with TSC as we anticipate more significant breakthroughs in clinical care in the future." Janie added, "We also hope to inspire others to join us and consider giving as well."

With this funding, the Frosts continue their dedication to the TSC community by leaving a living legacy that will lead to future advances.



Listen to Janie and Dr. Michael Frost on Episode 39 of the TSC Now podcast series at www.tscalliance.org/tscnow.

Special events



On April 3, the TSC Alliance hosted a spectacular record-breaking **20th Anniversary Comedy for a Cure®**, with Jazz Pharmaceuticals as headliner sponsor, **raising a whopping \$587,800** at the Avalon Hollywood in Hollywood, California.

It was our great honor to present the **Courage in Leadership Award** to **The Dinsdale Family**, who have been some of the organization's most dedicated supporters on behalf of their son Alex and all who are impacted by TSC. We were also thrilled to honor **Jo Anne Nakagawa** with the **TSC Champion Award** for her nearly three decades of dedicated service to TSC families and impacted individuals at UCLA and then the TSC Alliance.

The celebratory evening included musical performances and highlights from **Althea Grace**, a TSC mom and singer-songwriter who gained national attention as a contestant on *American Idol* Season 19. The night also featured uproarious comedy from our headliner **Caroline Rhea** and featured comedian

Brian Kiley, as well as hilarious interludes from our emcees **Wendy Liebman** and **Jim O'Heir**. We are also thankful to have had our auctioneer extraordinaire **Damon Casatico** on hand to lead our live auction, along with support from our Comedian Committee member **Mo Collins**.

The special anniversary event was sponsored by Jazz Pharmaceuticals, Andrea Maginn Memorial Trust, CVS Health, Tim & Kathi Dills, Horizon Therapeutics, Marinus Pharmaceuticals, Nobelpharma, Szilagyi Family, UCB Inc., WNC & Cooper Family, BridgeBio, Upsher-Smith Laboratories LLC, Keith A. Hall Family, Hobart and Shapiro Family and Ted and Peggy Mastroianni.

The next Comedy for a Cure is scheduled for April 2, 2023, so mark your calendar now!



Althea Grace



Joy and Chris Dinsdale



Jo Anne Nakagawa



Over the weekend of May 14-15, the TSC Alliance held our **20th Anniversary Step Forward to Cure TSC® Global Hybrid Walk-Run-Ride!** Over the past 20 years, the TSC community – including volunteers, sponsors, corporate partners and

advocates – has helped raise more than \$18.4 million at these annual events!

The success of this year's Step Forward to Cure TSC was a direct result of our strong community and extraordinary national planning committee, who worked for more than six months on this special anniversary event, including Shalonda Alexander, Andrea Beebe, Mary Jo Cardona, Danielle Clark, Lori DiStefano, Preston Fitzgerald, Cindy Fowler, Jonathan Goldstein, Shannon Grandia, Frances

Harper, Lesley Holmes, Jill Hyman, Karen Johnston, Jessica Krefting, Jenny Kuehn, Mary Ann Lamb, Heather Lens, Jack Lyons, Jessie Myers, Noor Panjwani, Lauren Perry, Mary Roberds, Lauren Shillinger, Alanna Spotts, Jackie Tallman and Carol Ann White.

We were also excited Los Angeles, Dallas and Philadelphia held live, in-person events. And the TSC Alliance is thankful to the local communities that hosted additional walks and gatherings.

National sponsors



TSC Warrior Sponsors: CVS Health, Hightower Dermatology, Hightower Veterinarian Services, Michael P. Wilson Inc. Real Estate Appraisers



TSC Champion Sponsor: Klace & Company Real Estate

TSC Crusader Sponsors: CRD & Associates, Baird, Soboba Foundation

TSC Defender Sponsors: Apex Title and Closing Services, Level Up Drywall

A record-breaking **29 TSC Clinic teams** participated in this year's event, including Atrium Health (NC), Beaumont Health, Boston Children's, Boston Children's Hospital Physicians, Children's Hospital Los Angeles, Children's National Medical Center, Children's Hospital of Orange County, Cincinnati Children's, Cook Children's, Dell Children's Hospital, Duke University, Herscot Center for TSC at

Massachusetts General Hospital, LeBonheur Children's, Lurie Children's Hospital, Minnesota Epilepsy Group, Nemours/duPont Children's, Penn State Children's, Seattle Children's Hospital, Stanford, Texas Children's, Texas Scottish Rite Hospital for Children, UCLA, University of Alabama Birmingham, University of Iowa, University of Maryland Medical Center, University of Texas Health Science Center Houston, UVA, Vanderbilt and Washington University St. Louis.

This year's prize winners include:

Most TSC Miles

Walk: Jean Leon Cong
Run: Jillian Scarr
Ride: Alfred Cooper



Special events (continued)

Largest Team

Corporate: Nobelpharma
Community: Noah's Holy Walkamolies

Most Funds Raised

First Place: Seraphina's Sweeties (Alex and Lesley Holmes, Team Captains), \$137,000 raised

Second Place: Team Jaye (Chelsea and Mary Ann Lamb, Team Captains), \$32,000 raised

Third Place: Bodies Buddies (Kaylan O'Hara, Team Captain), \$26,000 raised



Most Funds Raised by TSC Clinic:

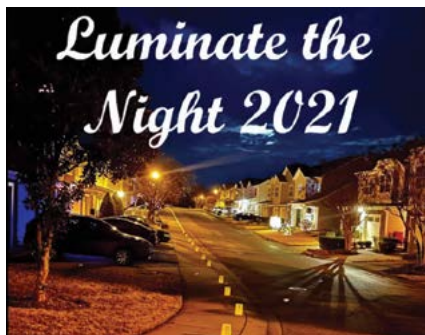
First Place: Seattle Children's Hospital, \$7,500 raised
Second Place: UCLA, raised \$3,000

Grand Prize Winner

Kayla Hunter of Team Eli from Schwartz Creek, MI

Other community campaigns

The following fundraisers were hosted by TSC champions between November 2021 through September 2022. Thanks to each of them for their support.



Luminate the Night

Hosted by Karen Johnston, Virginia Musselman and Mary Ann Lamb
December 18, 2021
Raised: \$14,975

4 Parker B

Hosted by Ryan and Andrea Beebe
May 21, 2022
Raised: \$22,000

Bike Blessing Service

Sponsored by Heaven's Saints Motorcycle Ministry
June 5, 2022
Raised: \$1,835



Dewey Beer Company Loves Parker B

Special thanks to Dewey Beer Company for donating \$8,156 of the total raised via staff tips at their Harbeson Delaware location.
Hosted by Ryan and Andrea Beebe
July 17, 2022
Raised: \$9,156

Dine and Donate – First State Brewing Company

Hosted by Ryan and Andrea Beebe
August 24, 2022
Raised: \$371.60 (20% net sales donated)

Cards For a Cure

Hosted by Margaret Cox
August 27, 2022
Raised: \$5,050

Heather Joy Memorial Golf Tournament

Hosted by Christy Buntrock
September 10, 2022
Raised: \$12,000 with 50% benefiting The LAM Foundation



Heather Joy Memorial Golf Tournament

Facebook Donations | Birthday Fundraisers

Thank you for supporting the TSC Alliance on your birthday or special occasions! January 1 to August 15, 2022
Raised: \$38,405

The TSC Alliance and **Team TSC** are proud to be an Official Charity partner with the TCS New York City

Marathon, which will be held Sunday, November 6, 2022. Congratulations and thanks to this year's Team TSC runners: Chip Burkhalter, Dr. Peter Crino, Jenny Kuehn, Bridget Lucas and Bridget Faria. The team has raised \$5,589 to date to advance the mission of the TSC Alliance. To support a Team TSC runner, please visit www.tscalliance.org/TeamTSC today.



Government advocacy

Congress clears \$8 million for TSCRP, additional \$8 million pending in House bill

After months of stalled negotiations, Congress last March enacted the fiscal year 2022 (FY22) Consolidated Appropriations Act, which included \$8 million in FY22 funding for the Tuberous Sclerosis Complex Research Program (TSCRP) at the Department of Defense (DoD). With this achievement, the total lifetime appropriation for the TSCRP now exceeds \$100 million (\$105 million from fiscal years 2002 to 2022)!

Thanks to our annual March on Capitol Hill and ongoing advocacy by the TSC community, Congress is on track to appropriate an additional \$8 million for the TSCRP in fiscal year 2023 (FY23). This funding was included in the FY23 Defense Appropriations Act approved on June 22 by the House Committee on Appropriations.

This success is due in large part to the bipartisan "Dear Colleague" letters circulated by Representatives Jamie Raskin (D-MD) and Markwayne Mullin (R-OK) in the House and Senators Martin Heinrich (D-NM) and Kevin Cramer (R-SD) in the Senate. The House letter was signed by 205 Representatives, and the Senate letter was signed by 35 Senators.

The overall process is likely stalled until after the November mid-term Congressional elections, but there is a good chance this legislation will be enacted sometime between the elections and the end of the year.

NIH slated for funding increases

The Consolidated Appropriations Act enacted last March also increased funding by \$3 billion for the National Institutes of Health (NIH) to \$45 billion in FY22. The Administration and Congress are now working on providing additional increases for NIH in fiscal year 2023, as well as new funding for the new Advanced Research Projects Agency for Health (ARPA-H).

On June 30, the House Committee on Appropriations approved its version of the fiscal year 2023 Labor-Health and Human Services-Education Act, which includes \$47.5 billion for the NIH. On July 28, the Senate released its version of the bill, which includes \$47.9 billion for NIH (including \$1 billion for ARPA-H). The House bill separately appropriates \$2.75 billion for ARPA-H.

Unfortunately, no additional action on the NIH budget has been taken since July, but House and Senate leaders will likely try to



negotiate their differences after the November elections. In addition to funding level differences, the House and Senate differ on where ARPA-H should be "housed" within the Department of Health and Human Services (HHS). The Senate proposes keeping ARPA-H within the NIH (where it is currently located for the time being), whereas the House proposes to move ARPA-H outside of NIH, where its budget and functions would be distinctly separate from NIH and its director would report to the Secretary of HHS. Regardless of how these differences are resolved, ARPA-H remains a promising new source of funding for discovering new therapeutics and cures for rare diseases like TSC.

Join our government action team

If you are interested in helping secure Federal funding for TSC research, simply email us at grc@tscalliance.org to find out how you can get involved.

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COVER STORY

2022 World TSC Conference in review—a hopeful, relentless, strong TSC community

BY SHELLY MEITZLER, Director, Community Education & Resources and Co-Chair, 2022 World TSC Conference



While excitement and anticipation always linger in the air leading up to the 2022 World TSC Conference, this year brought a newfound appreciation for being in person with the ability to high five or hug someone after the TSC community had relied solely on technology for support and resources for more than two years due to the COVID 19 pandemic.

The Hilton Anatole was filled by more than 900 speakers, in-person and virtual attendees, sponsors, exhibitors and staff members. The event was held July 28-31 at the Hilton Anatole in Dallas, Texas. The attendees came from 23 countries and 44 states for three days filled with educational sessions, social activities and just enough time to enjoy the on-site amenities, including a dip in the pool to ward off the relentless Texas temperatures.

The 2022 World TSC Conference was co-hosted by the TSC Alliance and TSC International (TSCi) with Title Sponsor Jazz Pharmaceuticals and Presenting Sponsor Nobelpharma. The three general sessions featured world-renowned TSC expert physicians, TSC family members and TSC Alliance science department members to highlight the participation of the community and the impact it has made to move TSC research forward.

In considering the needs and comfortability of those not able to attend in-person, the TSC Alliance offered a hybrid/online viewing option, which included the three general sessions, two general question-and-answer panels of presenters and three of the five learning paths: large group lecture, panel and specialty topic via livestream to include any conference participants from around the world who could not be in Dallas. This resulted in more than 150 viewers who were able to participate in the online sessions through live viewing and Q&A.

Topics included TSC-associated neuropsychiatric disorders (TAND) sessions to address areas of need across the

TSC lifespan for parent's, caregivers, young adults and adults. These sessions were highly attended, many with standing room only. Other sessions addressed alternative therapies, seizure management, kidney involvement, accessing managed and palliative care, educational advocacy, a Spanish Educational Meeting and Gathering and much more. Each learning path offered a different learning style that included formal or informal presentations and time for questions and answers to encourage audience participation.

The discussion group sessions were not live streamed or recorded to foster a conversational atmosphere with the ability to share personal information and have candid conversations. These sessions promoted active discussion and sharing by allowing participants to focus on topics such as sexual development for dependent and semi-independent adults, women's and men's health, mental health issues and relationships.

The other learning path included workshops that provided an actionable takeaway like a seizure action plan (SAP) or how to track behaviors for families looking for tools to implement at home to help with this issue. There was also a dedicated workshop for siblings ages 7-17, which was primarily hosted in the conference day camp managed by Corporate Kids Events (CKE).

CKE hosted the day camp at the 2006, 2014, 2018 and 2022 World TSC Conferences. Their services allow families to bring dependents of all ages and abilities to the conference and trust they are well-cared for during conference sessions. Campers enjoyed a myriad of activities – a magic show featuring Shane Brady along with his service dog Ralphie, an animal show and an onsite crafts and games. The camp hosted more than 120 TSC individuals and siblings while parents and caregivers attended sessions and had the opportunity to network with the attendees – some meeting others walking this TSC journey for the first time since their diagnosis.





The Teen Lounge, back by popular demand, offered teenagers the opportunity to bond over video games, shared interest in magic tricks and an assortment of drinks and snacks to fill the time. The unstructured nature of the lounge allowed teens to have someone sitting next to them who understood a little of what it feels like to walk in their shoes. They left on Sunday with new friends and connections of their own, some truly stepping out of their comfort zone to form lasting friendships.

Two of the most popular general conference sessions included TSC Community-Driven Research Network (TSC Alliance Research Model) and Global Collaborations (TANDem) and Updated Consensus Guidelines.

In addition to the robust, information-packed World TSC Conference agenda, additional meetings were held leading up to and during the event. The TSC Alliance Nurse Symposium for Advanced Practitioners and Nurses served as a valuable virtual and in-person program for those treating and coordinating TSC patient. It provided insight on the latest developments in multidisciplinary treatment. Participants left with an understanding of innovative clinical and practical strategies in an interactive format that fostered discussion. The goal is to improve clinical outcomes for patients by enhancing communication with the healthcare team.

In addition, TSCi hosted its annual workshop the day before the 2022 World TSC Conference. Representatives from associations in Belgium, Brazil, Canada, Denmark, France,

Germany, Hungary, India, Ireland, Israel, Italy, Mexico, Poland, Portugal, Serbia, South Africa, United Kingdom and United States participated. The workshop focused on global clinical trials in TSC, international TSC advocacy and TANDem. It was the first in-person TSCi meeting since 2019.

New for 2022, the TSC Alliance sponsored a research room. TSC community members were able to explore ways to participate in clinical research, including the TSC Alliance's Biosample Repository and Natural History Database. With participant consent, staff from Phlebotek, a mobile phlebotomy company, were on hand to collect blood samples from individuals with a TSC diagnosis.

The opening dinner on Thursday night allowed TSC Clinic Directors Steve Sparagana, MD; M. Scott Perry, MD; and Hope Northrup, MD, along with the help of the TSC Alliance staff; to surprise Kari Luther Rosbeck, TSC Alliance President and CEO, with the Manuel R. Gomez Award. A new \$2.5 million gift to support TAND research was also announced.

Even with the packed hours of 7 am to 5:45 pm, the days did not end after each day's closing general question-and-answer panels. Following large group dinners, attendees dispersed to various after-dark activities for TSC adults, teens, TSC moms, TSC dads, international attendees and more. These activities facilitated connections between TSC communities around the world and were extremely well attended.

The closing "Blue Night" prom-themed Saturday night dinner program began with opening remarks from Kari Luther

Rosbeck and celebrated Lisa Moss, Vice President, Donor Relations, on her 10 year anniversary with the TSC Alliance.

The program included honoring Dr. Michael and Janie Frost with the TSC Champion of Hope Award for their devoted careers and lives to helping those individuals and families living with TSC. The night ended with the ever-popular DJ P-Love, who had everyone on the dance floor all night. Paired with a photo booth, it was a night to remember.

Sunday concluded the conference with a half day including one set of breakout sessions and an inspiring closing session, Driving the Future of TSC Clinical Trials and Clinical Care. Because the impact of TSC clinical trials provides hope for the future, the session ended with a call to action for continued community participation. Many attendees departed for their journeys home with long hugs and hopeful hearts.

As always, the inspiring sessions and activities gave hope to all participants. In-person and virtual participants were able to learn about the latest TSC diagnostic, treatment and management and a better understanding of the impact on the progress of TSC research. Of course, the TSC Alliance is deeply grateful to the 58 sponsors who made the 2022 World TSC Conference possible.

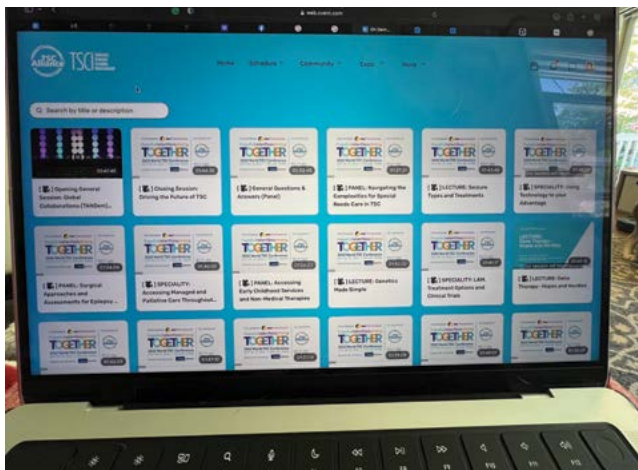
Our attendees left with a profound appreciation of new tools, coping skills and relationships to take back to the TSC communities across the globe feeling empowered by the knowledge and information shared. But most of all, the feeling of unconditional love and support felt throughout the event are a true inspiration. Thank you for joining us for this momentous event!

Despite the challenges of the past few years, the global TSC community remains hopeful, relentless and strong.



Thanks to our 2022 World TSC Conference sponsors

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View the 2022 World TSC Conference general and educational sessions online

Virtual and in-person conference attendees can watch the three general sessions, two general question-and-answer panels of and three of the five learning paths: large group lecture, panel and specialty topic online at tscalliance.org/2022AttendeeHub.

Recorded sessions will be available to the public for viewing on the TSC Alliance website in January 2023.



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A beneficiary doesn't have to be a person – it can be an organization whose mission you want to continue long after your lifetime. When you name TSC Alliance Endowment Fund as a beneficiary of your retirement plan assets, life insurance policy or donor advised fund, you can make a big impact on our future.

And you can do it simply by filling out a form.

You can name TSC Alliance Endowment Fund as beneficiary of many different types of accounts, including:

- **Retirement plan assets.** When left to loved ones, these assets are subject to income tax. When left to us however, they pass tax-free, allowing us to put 100 percent of your gift toward achieving a future where every person and family affected by TSC has what they need to live their fullest lives.
- **Life insurance policy.** Perhaps your children are now grown and you

have a life insurance policy you no longer need. Consider naming us as beneficiary. This gift allows you to make a substantial donation at a relatively low cost.

- **Donor advised funds.** If you have a donor advised fund, you can recommend grants to our organization during your lifetime and name the TSC Alliance Endowment Fund as the beneficiary to receive the balance of your account after your lifetime.

Four steps to the gift of a lifetime

- 1. Contact** your administrator to request a change-of-beneficiary form or download a copy from its website.
- 2. Fill out** the form listing the TSC Alliance Endowment Fund and the amount or percentage you'd like us to receive on the form.
- 3. Return** the form to your administrator. (Be sure to keep a copy for yourself as well.)

- 4. Let us know** about your gift! It would be our honor to thank you and if your donation is to the TSC Alliance Endowment Fund, welcome you into the Eternal Flame Society

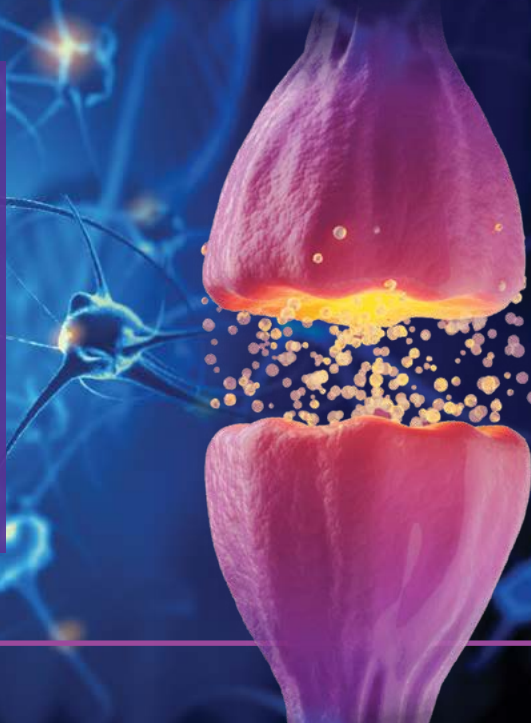
Tip: Beneficiary designations can be updated at any time to meet your changing needs. Make sure you review your beneficiaries regularly to ensure they go where you want them to.

Take the next step

Need help getting started? Contact Lisa Moss, Vice President, Donor Relations, at (301) 562-9890 or lmoss@tscalliance.org today for help finding the perfect way to leave a lasting legacy.

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Basimglurant, a new mechanism of action for the control of seizures in tuberous sclerosis complex?



In 2018, scientists at Harvard Medical School performed a series of experiments in an animal model, discovering a new mode of action with potential for treating seizures associated with tuberous sclerosis complex (TSC). This experiment showed an effect on seizure control by decreasing the neuronal activity at a receptor in the brain called metabotropic glutamate receptor 5 (or mGluR5 for short).

The experiments showed a significant reduction in the duration of seizures and suggests that decreasing activity at the mGluR5 could be used in treatment of epilepsy associated with TSC. In the same experiment scientists also observed an effect on normalizing the elevated synaptic protein synthesis, which leads to tumor formation and progression in TSC.

Because of this dual effect – decreasing the activity at mGluR5 receptors to both reduce the seizure duration and to normalize the protein synthesis – scientists believe basimglurant, a substance which has a very strong effect on down-regulating mGluR5, could be providing TSC-specific seizure control. As a result of that, Noema Pharma (Basel, Switzerland) has initiated a clinical trial to investigate whether the effect seen in the laboratory may also be seen in TSC patients. The trial is named Galene, after a Greek goddess of calm seas, as it reflects Noema’s ambition to contribute to calming the overexcited neural connections leading to seizures in people with TSC.

In recent years, basimglurant has been studied in people with two different conditions (Depression and Fragile X syndrome) and in these trials was found to be safe. More than 300 adults and 70 adolescents and children over 5 years received the drug either once or repeatedly. Overall, basimglurant was well tolerated.

The Galene study is the first clinical trial to investigate basimglurant in people with TSC and has been designed to answer a few key questions:

- Does the drug adequately control seizures?
- What is the optimal dose?
- Is the drug safe in people with TSC?
- Additional questions deemed important to patients and their families such as overall impression of TSC symptoms change, impact on functioning and the most impactful symptoms.

Children (5 years and older), adolescents and adults up to 30 years of age may be able to participate in the study, if their seizures associated with TSC are not sufficiently controlled by their current treatment.

“Noema is truly patient centric. Their collaborative approach focusing on the needs of individuals with TSC aligns very well with our goals to provide earlier diagnosis and offer better treatments so everyone living with TSC can live their lives to their full potential.”

– Steven L. Roberds, PhD, Chief Scientific Officer, TSC Alliance

The study medicine is contained in a capsule that is taken by mouth. Each day, the participant will take 4 capsules with breakfast. Should they be unable or unwilling to swallow the capsules, the capsules can be opened and the contents sprinkled on apple sauce.

The Galene study is comparing basimglurant with placebo and measures how effective basimglurant is in controlling seizures and how safe it is. It is a double blind placebo-controlled study, which means the treatments are randomly assigned and it's not possible to know whether the treatment given is basimglurant or placebo.

An electronic seizure diary will be used to record seizures and measure the impact of basimglurant on the frequency, severity as well as number of days without seizures.

The study has two parts. After completion of part one (a 30-week double blind study), those having positive treatment effect and are interested to continue will be offered the possibility to carry on with the study treatment for another 52 weeks. All participants will receive the active medication during the second part of the study. (See Figure 1 below.)

As with any investigational drug, basimglurant might cause unwanted side effects. It's therefore very important that not only the doctor but also the parent/caregiver and the participant themselves watch out for any changes in how they feel or behave and that any changes are reported. To make sure the benefits but also the risks are well understood, Noema has developed study materials appropriate for adults and for children. The materials describe the study and what is required when taking part including details regarding how to monitor the side effects.

Each trial participant will be observed in the doctor's clinic at regular intervals where physical and mental health status assessments will be performed drawing blood and urine

samples for laboratory analysis. Between the clinic visits there will be checks done by the doctor to record and address any unexpected events remotely.

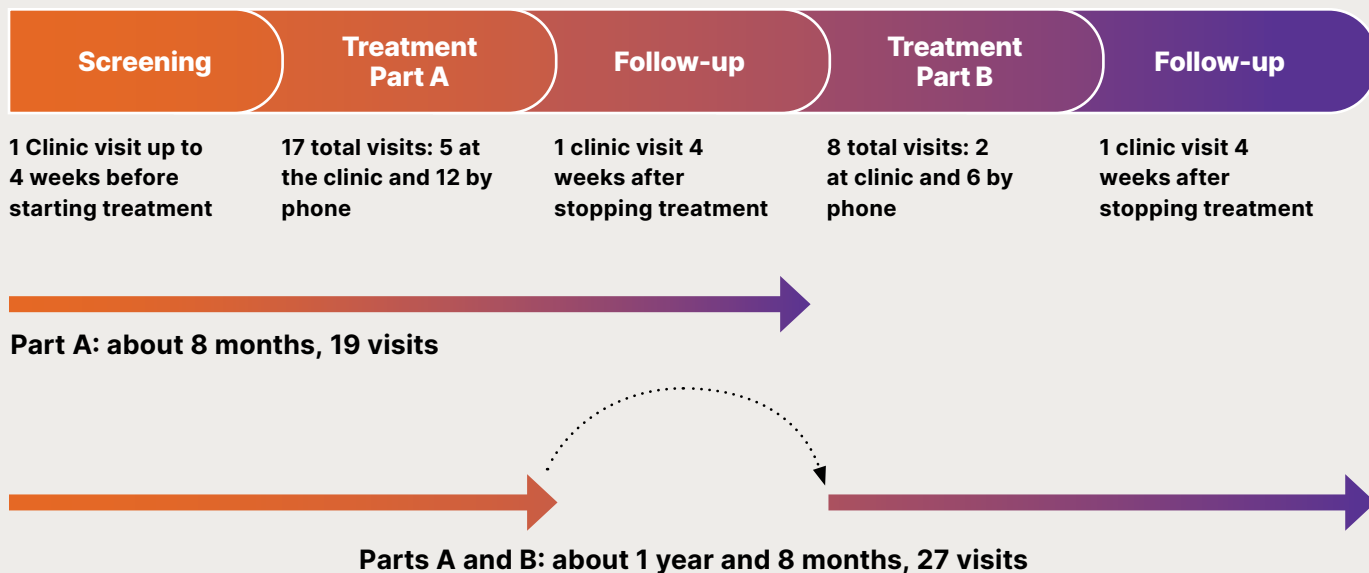
The Galene study is currently open for enrollment in the US, Israel and Australia. Further sites will follow in the UK, Turkey, Spain, Italy and India.

Disclaimer: This is not to be considered as a promotion of Noema's compounds nor as a solicitation to use its products as none of Noema's investigational drugs have been reviewed or approved by health authorities. Basimglurant is an investigational product and has not been approved by any health authorities.

Where to learn more

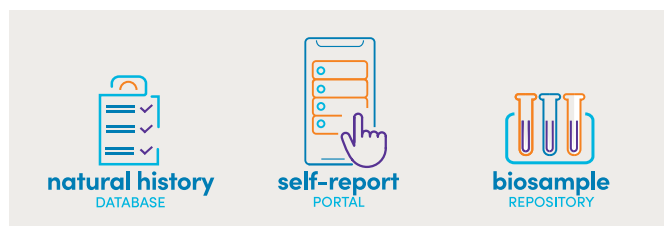
- To learn more about basimglurant, watch the recent TSC Alliance webinar at www.tscalliance.org/basimglurant.
- For more information including the list of hospitals participating in the study in the US, please contact Ashley Ponders, MSN, FNP-C, Director, Medical Affairs at the TSC Alliance, at aponders@tscalliance.org.
- For further information, visit www.clinicaltrials.gov and enter **NCT number NCT05059327**.
- To find out more about Noema Pharma, visit www.noemapharma.com.

Figure 1: Study Overview



Your participation accelerates TSC research

Learn how you can contribute to ongoing research projects at the TSC Alliance by reading our frequently asked questions (FAQs) below. We are committed to supporting inclusive participation in research on TSC – if you or a loved one are interested but concerned about any aspect of the project, please contact us to discuss potential flexibility.



TSC Natural History Database, Biosample Repository and Self-Report Portal FAQs

What is the purpose of these research initiatives?

The purpose is to accelerate research on TSC biology and drug development with the long-term goal of improved clinical care. We aim to do this by collecting information about people with TSC over their lifetimes and collecting biosamples from people with TSC.

What is a biosample?

A biosample is a sample of biological material, such as a tube of blood or a piece of tissue taken during surgery or a biopsy.

What types of samples are collected?

We collect blood, buccal (cheek) cells and leftover surgical tissue samples to support TSC research.

How does the TSC Alliance collect my sample?

We contract with mobile phlebotomy services that can send a trained and licensed person to the participant's home

to collect the blood or allow participants to visit a partner site such as Quest Diagnostics for the blood draw that ship it to our biorepository. Biosamples may also be collected at select TSC Clinics.

Where will my sample be stored?

All biorepository samples are stored at the Van Andel Research Institute in Grand Rapids, Michigan.

What types of information will be collected and where will it be stored?

We will collect data such as your date of birth, race, height, weight, test results and details about medications, procedures and TSC-associated conditions. We will contact you periodically to request updated medical information. All medical information will be tied to your unique identification number and stored securely within our database.

How will my sample(s) and data be used?

Research studies will use your biosample(s) and medical information to better understand TSC. This project will provide valuable resources that may help identify new targets for drug development or biomarkers that can be used to predict an individual's risk for developing specific TSC manifestations. All researchers must apply for biosample access and be approved by the Natural History Database (NHD) and Biosample Repository (BSR) Steering Committee.

What if I have already submitted a sample?

The TSC Alliance needs to expand our biosample collections, including storage of multiple biosamples from the same individual over time. We can connect your new sample to your established unique identification number.

Will I be notified if something is found in my sample?

The TSC Alliance will provide news and summaries of research studies using specimens from the TSC Biosample Repository and data from the Natural History Database on our website, publications such as *Perspective* magazine and electronic communications such as *TSC Matters*.

Be represented – we need your help to ensure our research represents the diverse experiences of individuals impacted by TSC.

Sequencing of your DNA may be completed as part of this project. This genetic information will then be analyzed to look for changes, or variants, within genes known to cause TSC (*TSC1*, *TSC2*). We may be able to provide genetic results back to you. If your sample is utilized and you elect to receive results back, we may issue you a report with these specific results. These data will be stored and shared with other researchers using your de-identified unique identification number.

You may elect on your consent form if you are interested in receiving data should it become available. *Please note: We cannot guarantee your sample will be used in a study that offers results back to participants.*

How do you protect my privacy?

We are committed to respecting the privacy of all individuals who participate. Here are some ways we protect your privacy while participating in our research projects:

Your biosamples and data are coded with a unique identification number that is randomly generated when we enter clinical information from your medical records in the TSC Natural History Database. We will keep the list that links this reference identification to your name separate from your biosample and clinical information; only the principal investigator (Gabrielle Rushing, PhD) and research staff conducting the project will have access to this list.

We use a cloud-based, HIPAA-compliant platform that encrypts all data for the NHD called Studytrax (www.studytrax.com). To ensure data is secure and reliably available, enterprise class hosting facilities are utilized to power Studytrax.

Researchers who study your biosample and clinical information will not know who you are. They must also sign an agreement that they will not try to find out who you are.

Your privacy will be maintained as confidentially as possible within the limits of the law. The TSC Alliance has a "Certificate of Confidentiality," which is issued by the National Institutes of Health, that protects us from being forced to give your name and any personal information about you in any civil, criminal, administrative, legislative or other proceedings, at any level of government, while the certificate is in effect. The protection of the Certificate lasts in perpetuity.

What is the TSC Self-Report Portal (SRP)?

The TSC community is pivotal to advancing research, and this is one major reason why the TSC Alliance is excited about the SRP. This portal permits the collection of patient-reported outcomes (PROs) on a variety of topics related to tuberous sclerosis complex. PROs are any report of the status of a

person's health condition that comes directly from the person, without interpretation of the person's response by a clinician or anyone else. In the case of individuals with TSC who are unable to speak or report for themselves, PROs can be submitted by their parent, guardian or caregiver. The type of PROs will vary by study and studies will be continually added into the portal. The data entered is connected to data and samples in the NHD/BSR using your same unique identification number.

The purpose of your participation is to help the TSC Alliance and TSC researchers better understand the perspective of those affected by TSC so we can begin to track changes and measure improvement in areas most important to you. Currently, we have questions related to TSC-Associated Neuropsychiatric Disorders (TAND) in the portal with plans to incorporate new questions this Winter.

What results have come from the project?

Sample distribution to researchers began in 2018. To date, portions of **1,823** samples have been distributed to **40** distinct researchers for **46** distinct projects. Highlights include:

- **One** publication using brain tissue from the repository has been published.
- **13** publications have been published using NHD data.
- **12** Seed Grants (funds up to \$20,000) have been distributed to researchers to utilize BSR samples.

Marinus Pharmaceuticals utilized plasma samples in a pilot study that led to the initiation of a Phase 2 clinical trial of ganaxalone for epilepsy in TSC. This study is now moving forward with Phase 3.

If you are interested in participating in these projects or have questions, please email biosample@tscalliance.org.

Why did you participate in the NHD/BSR project?

"In the midst of the Covid-19 pandemic, Bella was diagnosed at 6 months old with infantile spasm seizures, polycystic kidney disease and high blood pressure. As a first-time new mom, I had no idea what the future held . . . but she is overcoming obstacles. She is special. I chose to participate in the Biosample Repository because I was asked by caring people in similar situations, and it is the right thing to do for her. Bella is just one of many children who build the future of our world."

—Christine Gomes, mother to Bella



Our experience at the 2022 World TSC Conference

Iris Mustich and Danielle Clark are both volunteer TSC Alliance Adult Regional Coordinators (ARCs) who attended the 2022 World TSC Conference in Dallas. We asked them each to tell us a little about themselves and reflect on their experiences at the conference and what pieces they found to be most impactful.

Iris Mustich

My name is Iris Mustich. I am 28 years old and was diagnosed with TSC as a young child after I started having focal seizures. I live in Durham, NC, and currently work at a nonprofit as a Clinical Research Manager.

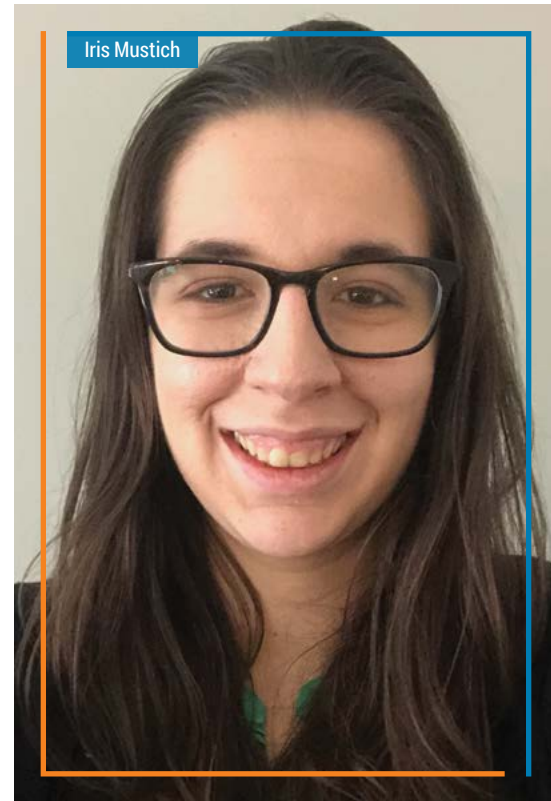
I serve as the Adult Regional Coordinator for the Northeast, where I grew up. I became involved as an ARC last year, and I am so grateful for the support and friendship of Danielle and the rest of our ARC team. It can be easy to feel isolated as an adult with TSC, and I am happy I can build relationships and help connect other adults with resources. I am passionate about advancing research, improving the patient care experience and supporting the adult TSC community.

I attended the World TSC Conference for the first time this year, and I am so glad I did. It was truly inspiring to see so many adults, families, physicians and advocates come together from all over

the world. For me, the most impactful moment at the conference was at the opening dinner when Anita Bhatia announced the \$2.5 million gift to the TSC Alliance – the largest single donation in its history – to establish Anya's Accelerator to drive TSC-associated neuropsychiatric disorders (TAND) research and develop new treatments. Thinking about how far we have come since I was diagnosed in the 1990s and seeing the emotion of the clinicians, families and advocates in response to this announcement gave me chills.

Women's health is an area in TSC that has significant gaps in both research and clinical care; I am honored to have been part of a conversation on the topic at the conference. It was incredible to see how many people wanted to engage on the topic – there was standing room only! This really drove home how important a topic this is and why it is important to further invest in research and education on women's health. Another thing that struck me about the session was how several clinicians chose to participate, even though women's health is not their specialty. This gives me hope that more women with TSC will have physicians who are aware of the concerns they may have and who are better equipped to support their patients.

While I greatly enjoyed attending the sessions and learning more about TSC, it was also important for me to meet



and connect with others in the TSC community. Finding people who can not only share resources or know when to lend a listening ear, but who can truly empathize with what challenges we may face, is rare outside the TSC community. Having connections with others who have had similar experiences and understand the complexities of life with TSC is invaluable.

Danielle Clark

My name is Danielle Clark. I am 46 years old and was diagnosed with TSC at 29. I have complex partial seizures and confetti spots/ash leaf markings. I live in San Antonio, TX, working as a Renal Dietitian.

In my role as an ARC, I am able to help others find help with medical support and get answers to general questions about their diagnosis. I had a number of questions when I was diagnosed, and it is great to be able to turn the table to now help others. The group of ARCs is a wonderful support system,

and I continue to learn from them and their experiences.

This was my first year attending the World TSC Conference, and it was outstanding. I had heard the World TSC Conference was wonderful, and it lived up to its reputation with multiple educational sessions, the world's top TSC

experts and other opportunities to learn about various topics.

As most everyone knows, TSC manifests in so many ways – no two people are the same – yet there are many similarities. In that vein, the chance to attend sessions on research and then be able to talk with experts in person about my concerns and hear about other people’s experiences was immeasurable.

The session on women’s health was especially informative and many things stood out to me about that session. I am not a mother, so I cannot speak from that perspective. However, in listening to the mothers in attendance, there seemed to be much concern about when to start birth control, how estrogen might affect the use of epilepsy medications, the challenges of

lymphangioleiomyomatosis (LAM) and family planning issues.

Of course, reproductive development can be a challenging subject, especially regarding when to start birth control as well as how epilepsy medications may affect pregnancy for women with TSC.. Personally, I had catamenial epilepsy for a while, until my medication stabilized my seizures without birth control.

TSC is overwhelming, regardless of its presentation – mild, moderate or severe. This is why I believe having connections within the TSC community helps us to know each other better and lift each other up. To that end, I am passionate about serving the TSC community whether it’s fundraising or offering one-on-one support, but I especially enjoy assisting the adult TSC community.



Danielle Clark

Nobelpharma America is committed to those with rare diseases

Nobelpharma America, LLC believes in bringing innovative products to those who need them and supporting people at every stage of their treatment journey. Furthering its mission to contribute to society by delivering critical but neglected pharmaceuticals and medical devices, the company recently announced the launch of Nobelpharma Connect, a patient support program offering resources and co-pay services to help eligible individuals with access and information during treatment management.

Nobelpharma America aspires to provide services and support to help meet the changing needs of those with rare diseases. For more information about Nobelpharma America, go to www.nobelpharma-us.com. Nobelpharma America is a wholly owned subsidiary of Nobelpharma Co., Ltd., Tokyo, Japan.

Nobelpharma



Thoughts from a Future Leader

Pensamientos de una Futura Líder

Can you tell us a little bit about yourself and your journey with TSC?

My name is Natalia and I'm from Mexico City. I was diagnosed with TSC at birth, but I did not have any seizures until I was about 11 years old. When I was a teenager, the seizures started to get worse until my neurologist found the correct dose of medicine. I'm grateful I haven't had any seizures in the last three years.

¿Puede contarnos un poco sobre usted y su viaje con TSC?

Mi nombre es Natalia y soy de la Ciudad de México. Me diagnosticaron TSC al nacer, pero no tuve convulsiones hasta los 11 años. Cuando era adolescente, las convulsiones comenzaron a empeorar hasta que mi neurólogo encontró la dosis correcta de medicamento. Estoy agradecida de no haber tenido ninguna convulsión en los últimos tres años.

You attended the World TSC Conference in Dallas this year with your parents – what was most impactful for you about the experience?

For me, the most impactful part of my experience at the World TSC Conference was to connect with more families looking for answers and help from other community members. I saw a lot of new people, mainly children with TSC and their parents, trying to understand what TSC really is. Another thing that was impactful for me was feeling like I was

in a place where I really belong, because I felt understood by people my age there and I can be a role model for other families and individuals with TSC.

Asististe a la Conferencia Mundial de TSC en Dallas este año con tus padres. ¿Qué fue lo más impactante para ti de la experiencia?

Para mí, la parte más impactante de mi experiencia en la Conferencia Mundial de TSC fue conectarme con más familias que buscaban respuestas y ayuda de otros miembros de la comunidad. Vi a mucha gente nueva, principalmente niños con TSC y sus padres, tratando de entender qué es realmente el TSC. Otra cosa que me impactó fue sentir que estaba en un lugar al que realmente pertenezco, porque me sentí comprendida por las personas de mi edad y puedo ser un modelo a seguir para otras familias e individuos con TSC.



Natalia Zarazua

It was your dad's first time attending the event – what was that like for you to have him there?

To have my dad there was awesome. He also has TSC, but he does not have any symptoms like mine. Having him by my side made me feel more understood and supported by him. I felt stronger than ever beside him – and my mom as well.

Era la primera vez que tu papá asistía al evento. ¿Cómo fue para ti tenerlo allí?

Tener a mi papá allí fue maravilloso. También tiene TSC, pero no tiene ningún síntoma como yo. Tenerlo a mi lado me hizo sentir más comprendida y apoyada por él. Me sentí más fuerte junto a él y junto a mi mamá también.

What was your favorite story/activity from the World TSC Conference?

In just four days I met many people and heard different stories. To be honest, some of them shocked me and made me feel fortunate. Some others made me feel hopeful about life with TSC and the future for every child or young adult.

For example, I met a young adult who finished his bachelor's in science degree, lives alone, has traveled with his friends to many countries, has TSC and is part of the Future Leaders program. That made me feel hopeful, because it made me realize everything is possible for young adults like me.

The stories of all the mothers from Latin America also gave me hope. The way they have a lot of energy and the way they want to get as many information as they can so they can give their children the best life made me realize that behind every child, there's a mom struggling and fighting day by day looking for answers and ways to treat their kids just like any other child.

¿Cuál fue su historia/actividad favorita de la Conferencia Mundial de TSC?

En solo cuatro días conocí a mucha gente y escuché diferentes historias. Para ser honesta, algunos de estas historias me sorprendieron y me hicieron sentir afortunada. Algunas otras me hicieron sentir con esperanza sobre la vida con TSC y el futuro de cada niño o adulto joven.

Por ejemplo, conocí a un adulto joven que terminó su licenciatura en ciencias, vive solo, ha viajado con sus amigos a muchos países, tiene TSC y es parte del programa Future Leaders. Eso me hizo sentir esperanzada, porque pude darme cuenta de que todo es posible para los adultos jóvenes como yo.

Las historias de todas las mamás de América Latina también me dieron esperanza. La forma en que usan toda la energía que tienen y la manera en que quieren obtener la mayor cantidad de información posible para poder darles la mejor vida a sus hijos me hizo darme cuenta de que detrás de cada niño, hay una mamá que lucha día a día buscando respuestas y formas de tratar a sus hijos como cualquier otro.

Why do you think it's so important to connect with others in the TSC community?

I think it is important to connect with the TSC community because we can help each other. It doesn't matter if it is just listening to their stories — we may change their perspective of TSC, and they can change ours too. We help each other by having those connections.

¿Por qué crees que es tan importante conectarse con otros en la comunidad TSC?

Creo que es importante conectarse con la comunidad de TSC porque podemos ayudarnos unos a otros. No importa si solo se trata de escuchar nuestras historias, podemos cambiar la perspectiva acerca de TSC y otras personas también pueden cambiar la nuestra. Nos ayudamos unos a otros al tener esas conexiones.

What are you most passionate about as a TSC advocate?

I can make you a whole list of what I'm most passionate about as a TSC advocate, but right now I am focused on ways I can advocate to support other young adults like me. I can understand what it means to live with TSC, which other people don't. I know how hard it is to grow up feeling different than your friends and family, which can be hard to express. So, if I have to choose one thing that I am most passionate about, it would be the empathy I can share with the TSC community.

¿Qué es lo que más le apasiona como defensor de TSC?

Puedo hacer una lista completa de lo que más me apasiona como defensora de TSC, pero en este momento solo me puedo enfocar en las formas en que puedo apoyar a otros adultos jóvenes como yo. Esto se debe a que puedo entender lo que significa vivir con TSC, lo que otras personas no entienden. Sé lo difícil que es crecer sintiéndose diferente a nuestros amigos y familiares, lo cual puede ser difícil de expresar. Entonces, si tengo que elegir algo que me apasione, es la empatía que comparto con la comunidad de TSC.

If you could share one piece of advice with another young adult in the TSC community what would that be?

Now, that's a question I have to think about. If I can summarize it in one sentence, it would be "No one is you, and that is your biggest power." All of us have a different story, a different fight we are taking on, and that doesn't make us less than anyone else. In fact, it makes us resilient.

Si pudieras compartir un consejo con otro adulto joven en la comunidad TSC, ¿cuál sería?

Esta es una pregunta en la que tengo que pensar. Si pudiera resumir el consejo en una frase, sería: "Nadie es como tú, y ese es tu mayor poder." Todos nosotros tenemos una historia diferente, una lucha diferente que estamos asumiendo, y eso no nos hace menos que nadie. De hecho, nos hace resilientes.



TSC Alliance and Ramesh and Kalpana Bhatia Family Foundation announce new TSC research collaboration

During the opening of the 2022 World TSC Conference in Dallas, Anita Bhatia, MHA, Executive Director of The Ramesh and Kalpana Bhatia Family Foundation, announced a new collaboration with the TSC Alliance, working together to uncover biomarkers, test new treatments and connect researchers with families to better address TSC-associated neuropsychiatric disorders (TAND), which impact nearly everyone living with tuberous sclerosis complex (TSC). The \$2.5 million foundational gift is the largest single donation in the TSC Alliance's history.

This new funding will create "Anya's Accelerator," which will focus on furthering TAND translational research. TAND includes a wide range of cognitive, behavioral and psychiatric challenges linked to the disease's effect on brain function. Autism spectrum disorder, intellectual disabilities, neuropsychological deficits, aggressive behaviors and more can severely affect people with TSC and their families. However, much is still unknown about TAND issues and how to effectively treat them, hence the need for more targeted research.

"The TSC Alliance is incredibly grateful to The Ramesh and Kalpana Bhatia Family Foundation for this historic donation," said Kari Luther Rosbeck, President & CEO of the TSC Alliance. "We know TSC-associated neuropsychiatric disorders are incredibly challenging for people with TSC and their loved ones, and this funding will give us the ability to start finding answers and, hopefully, identify effective interventions."

"Clinical trials for treating TAND are challenging for many reasons, particularly because TAND affects different people in different ways," explained Steven L. Roberds, PhD, Chief Scientific Officer at the TSC Alliance. "This program will work to overcome these challenges by developing ways to measure the most impactful aspects of TAND for each individual and identifying biomarkers to enable targeting of specific treatments for care of specific individuals."

The three-year "Anya's Accelerator" research program will focus on three major goals:

1. Developing quantifiable patient-reported outcomes for the most impactful aspects of TAND utilizing the combined expertise of individuals and families living with TSC and clinical researchers;
2. Identifying biomarkers and predictors of specific aspects of TAND through collaborative and inclusive analysis of existing samples and data; and
3. Improving the translatability of and testing candidate drugs in TAND-relevant animal models by incorporating biomarkers or predictors relevant to those identified in humans.

"We are so grateful for the work and progress the TSC Alliance has made over the past 20 years. Anya's Accelerator will provide an opportunity to advance TAND research and innovation and offer hope for improved treatments, cures and prevention methods for those diagnosed with TSC and other neurological conditions," said Anita Bhatia, MHA. "This is our foundation's most meaningful and personal partnership to date, as my daughter, Anya, was diagnosed with TSC at eight weeks old. Without the incredible work of the TSC community and the development of new treatments that were studied and approved, her livelihood would have been gravely different."



You can hear more from Anita Bhatia, MHA, about this amazing gift and the project during Episode 38 of the TSC Now podcast series at www.tscalliance.org/tscnow.

TSC Now offers wide range of topics

TSC Now



a podcast from



Now in its third year, the TSC Alliance's *TSC Now* podcast series continues to provide listeners with the latest on current tuberous sclerosis complex (TSC) clinical trials, updates in research and important information about upcoming TSC Alliance events and initiatives. Each month host Dan Klein, Director, Digital Platforms, has in-depth conversations with leading TSC researchers and clinicians, volunteers from the TSC community and families and individuals affected. *TSC Now* is the only podcast about tuberous sclerosis complex, the unique journeys of people in the TSC community and the hopeful future for everyone living with TSC. *TSC Now* is made possible in part by a sponsorship from UCB Inc.

Here is a summary of 2022 episodes to date:

Episode 32: The 2022 World TSC Conference

In the first episode of *TSC Now* in 2022, host Dan Klein provides an overview of the 2022 World TSC Conference, co-hosted with Tuberous Sclerosis Complex International (TSCi) July 28-31, 2022, in Dallas, TX.

Guest: Shelly Meitzler, TSC Alliance Director, Community Education & Resources

Episode 33: Noema, Basimglurant and a New Clinical Trial for Seizures in TSC

A Swiss biotech company, Noema, is investigating a novel substance which has shown some positive effects in laboratory models related to tuberous sclerosis complex (TSC). The company is setting up clinical trials to test whether the effect seen in the laboratory may also be seen in people.

Guests: Ype Elgersma, Erasmus Medical Center; John Kemp, Former Chief Scientific Officer at Noema; Ali Mostajelean, MD, Tuberous Sclerosis Clinic at UCSF Benioff Children's Hospital; George Garibaldi, Chief Medical Officer at Noema; Renata Lazarova, VP of Development, Pediatric Programs at Noema; and Steve

Roberds, PhD, TSC Alliance Chief Scientific Officer

Episode Sponsor: Noema Pharma

Episode 34: Celebrating 20 Years of Comedy for a Cure

Dan celebrates the 20th Anniversary Comedy for a Cure® on Sunday, April 3, at the Avalon in Hollywood, CA, learns about the past and present of this amazing event from some dedicated volunteers, and interviews one of this year's honorees.

Guests: Craig Shoemaker, Lisa Szilagyi and Jo Anne Nakagawa

Episode 35: The Past, Present and Future of Autism Research in TSC

Dan recognizes World Autism Month by taking a deep dive on the past, present and future of autism spectrum disorder (ASD) research in TSC.

Guest: Shafali Jeste, MD, Chief of Neurology and Las Madrinas Chair at the Children's Hospital of Los Angeles and Professor of Neurology and Pediatrics at Keck School of Medicine of USC

Episode 36: TSC Awareness Month

Dan recognizes TSC Awareness Month and the 10th Annual TSC Global Awareness Day and talks to two TSC dads registered for the 2022 World TSC Conference.

Guests: Ary Agami, President of the TSC Alliance of Mexico, and Guillermo Henrici.

Episode 37: The MILED Trial and the Future of LAM Research

Dan celebrates Worldwide LAM Awareness Month (#WWLAM) and raises awareness of lymphangioleiomyomatosis (LAM) and a pivotal clinical trial in LAM that is enrolling right now.

Guest: Frank McCormack, MD, Professor and Director of the Division of Pulmonary, Critical Care and Sleep Medicine at University of Cincinnati and former Scientific Director of The LAM Foundation

Episode 38: Galvanizing a World TSC Community

In a special two-part episode of *TSC Now*, Dan recaps the 2022 World TSC Conference, which was held in Dallas July 28-31, 2022. In part one Dan talks to two inspiring and visionary leaders in the TSC community.

Guests: Anita Bhatia, MHA, Executive Director of The Ramesh and Kalpana Bhatia Family Foundation, and Pete Crino, MD, PhD, Chair of the TSC Alliance Board of Directors and the Clinic Director at the TSC Center of Excellence at the University of Maryland Medical Center

Episode 39: Inspiring a World TSC Community

In part two, Dan explores the history of TSC conferences and speaks to dedicated volunteers who have shaped the TSC Alliance's past and will continue to shape its future.

Guests: Dr. Michael and Janie Frost and Preston Fitzgerald, former TSC Alliance Future Leader

Episode 40: Totally Super Cool!

Dan learns about a new children's book called *Totally Super Cool*, which was developed by Nobelpharma America, LLC.

Guests: Doug Looock, VP Head of Commercial Operations at Nobelpharma America, LLC, and Jonathan Goldstein, former TSC Alliance Future Leader

Episode Sponsor: Nobelpharma

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TSC Clinics “Up Close” Beaumont Children’s Hospital

In March 2016, the TSC Alliance recognized Beaumont Children’s Hospital in Royal Oak as the third TSC Clinic in Michigan and the 48th in the current network of 70 U.S. and 10 global TSC Clinics. This article continues an interview series about the healthcare professionals and staff who provide care and educational support to those affected.

The TSC Clinic Team at Beaumont Children’s includes:

Danielle A. Nolan, MD

Assistant Professor, Pediatric Neurology

Anne Marie Michon, MSN, RN, PNP-PC

Pediatric Neurology Nurse Practitioner in Pediatric Epilepsy

Paula Shock, RN, BSN

TSC Nurse Coordinator

Kelly Beaudry-Rodgers, MS, CGC

TSC Genetic Counselor

Dara Bell

Medical Assistant

Dr. Nolan, Beaumont Health received TSC Clinic designation in March 2016 with Co-Directors Dr. Donald J. Phillips and Nurse Practitioner Anne Marie Michon. At the time, you were completing

your pediatric neurology training at the University of Michigan Hospitals in Ann Arbor in June 2016. You continued there for another year to do an epilepsy fellowship, followed by a one-month rotation at Boston Children’s Hospital in July 2017. What was your experience at their TSC Clinic and how did it help with your transition to becoming the Director of the TSC Clinic at Beaumont after Dr. Phillips moved back to California ?

I was very fortunate to have the opportunity learn from both Dr. Patricia Robertson at University of Michigan and Dr. Mustafa Sahin at Boston Children’s regarding the care of children with tuberous sclerosis complex (TSC). Their compassion for patients and recognition that it is not “just” a pediatric disease helped to prepare me to direct the Beaumont TSC Clinic.

Tell us what motivated you to choose your career path.

Dr. Nolan: Going into pediatric neurology, I have always been captivated by the term “idiopathic.” When children develop neurologic conditions such as epilepsy or autism, most often the initial parent question is “why?” For patients with TSC, the active research and strong patient/family community have provided at least a starting point to this question. The amazing collaboration between families and physicians also has the potential to help children with various other neurogenetic

conditions. I am honored to be a part of this journey along with the families in our Beaumont TSC Clinic.

Pediatric Nurse Practitioner (PNP) Anne Marie: I have always, since childhood, loved helping people and teaching. I decided to combine both. I first became a Pediatric Registered Nurse and then obtained my master's degree in nursing as well as my teaching certificate. As a staff nurse I seemed to gravitate toward and always took care of children with epilepsy and other chronic health conditions including children who have TSC.

I went to school full time to obtain my master's degree in nursing at Wayne State University, while working full time as well as a registered nurse in pediatrics. My first clinical rotation in graduate school was in the Pediatric Neurology Division at Children's Hospital of Michigan. I loved interacting and caring for children with epilepsy and other neurological conditions including TSC and their families.

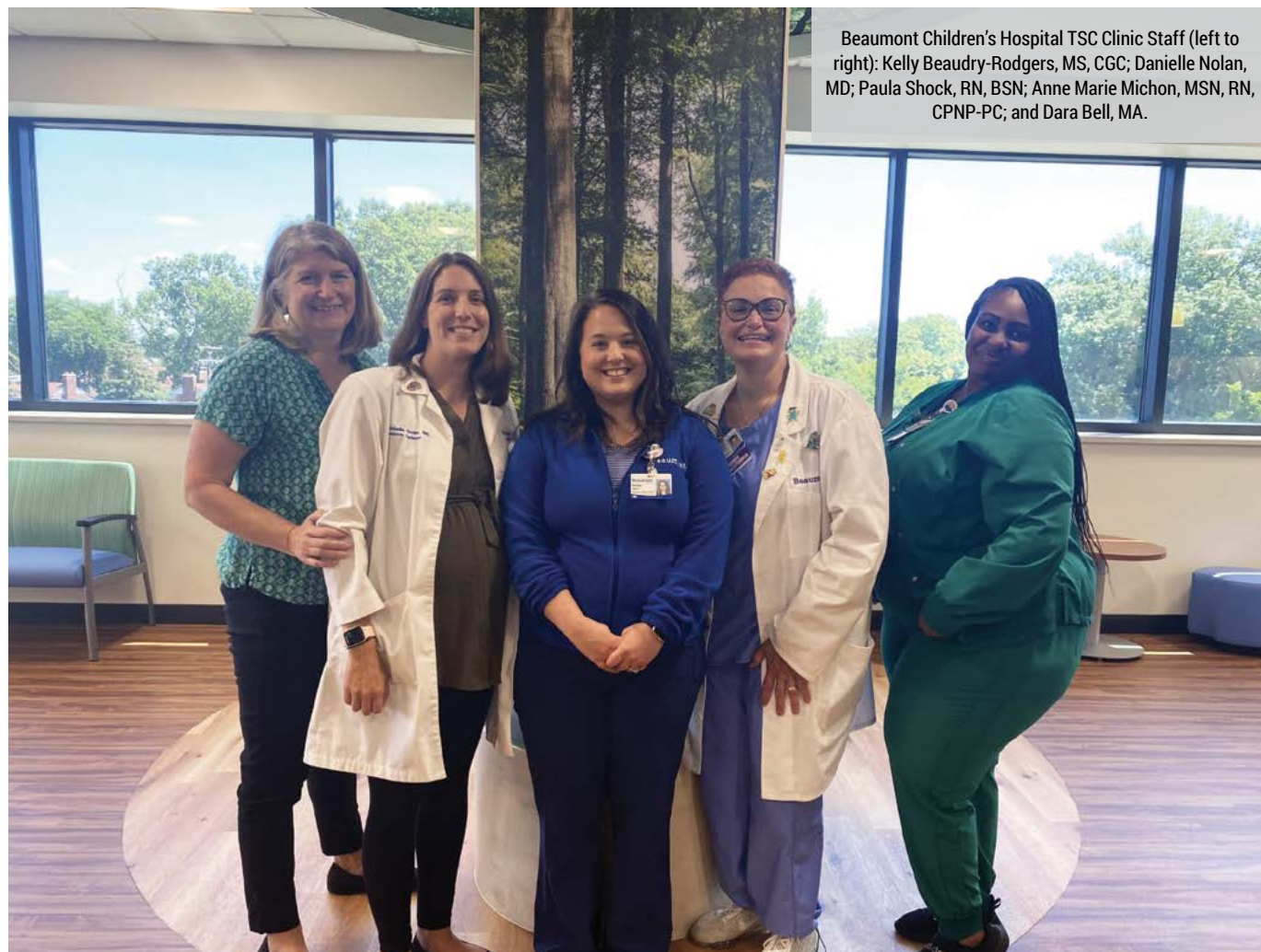
I was very fortunate that as soon as I graduated a position opened in the Pediatric Neurology Division and the rest is history!

Nurse Paula: I am a second-degree nurse having completed the accelerated BSN program at Wayne State University. My first degree is in political science. I found with previous jobs, I either felt challenged or rewarded, but not both, and wanted something more fulfilling. My sister is a nurse practitioner and encouraged me to explore nursing. I started taking prerequisite classes and working as a nursing assistant and fell in love with the job.

I never anticipated working in pediatrics, but it became clear it was my calling during my pediatric clinical rotation. I really enjoy working within the family unit to help positively impact our patients' health and wellbeing.

Kelly: I was drawn to the field of genetic counseling because of the mixture of science and social aspects of the position. There are always families to help through the process of understanding advances in genetic testing and adapting to the challenges of being diagnosed with a genetic condition.

Dara: Helping care for people has always been a passion of mine. I always strive to show acts of kindness to people who



Beaumont Children's Hospital TSC Clinic Staff (left to right): Kelly Beaudry-Rodgers, MS, CGC; Danielle Nolan, MD; Paula Shock, RN, BSN; Anne Marie Michon, MSN, RN, CPNP-PC; and Dara Bell, MA.

“We live in such a challenging time and insurance is not covering items needed by our patients as in the past. Providing access to care as well as making sure our patients are able to obtain their medications and equipment needed in a reasonable time frame are also challenging.”

are facing difficult situations pertaining to health. Whether it is complimenting them, remembering things they like to show that I remember them or sharing funny stories to make them laugh. An act of kindness can make a difference in adverse situations.

Dara, tell us more about your role in the TSC clinic.

As a Medical Assistant in the TSC Clinic I contribute by obtaining the medical history of the patient, coordinating and monitoring appointments, serving as a liaison on a daily basis by providing communication between the patient and support staff regarding symptom management and also facilitating provider efficiency in workflow.

Anne Marie, you are one of five nurse practitioners in the U.S. and Canada who is a Co-Director of a TSC Alliance-recognized TSC Clinic. Tell us how you and Dr. Nolan share responsibilities.

I consider it an honor to be a nurse practitioner who also co-directs a TSC Clinic. I feel I bring a unique perspective and skill set as a nurse practitioner to the role. Dr. Nolan and I both see patients in our TSC Clinic two Fridays a month. We see patients in collaboration as well as independently. This allows us to service more patients within our clinic. Dr. Nolan is an awesome provider and colleague. We also work closely with our epilepsy nurse and TSC coordinator Paula Shock. We as a team discuss patient issues, questions and concerns and call the patients and their families back.

How do you raise awareness about TSC within your institution or community?

Dr. Nolan: We recently had our first TSC Patient and Family Fun Day at Beaumont. Rare diseases such as TSC can be very isolating, not only for the affected person but their families

as well. By arranging a casual event I had hoped to bring together families that may be experiencing similar struggles or may be able to share personal success stories. We hope to continue this event yearly to not only raise awareness but provide a sense of community!

PNP Anne Marie: I participate with Dr. Nolan, Mrs. Shock and other colleagues within our division in the Step Forward to Cure TSC walk yearly. I also support our patients and their families in the TSC community with different activities they are doing. We hosted a TSC Patient and Family fun day in May 2022 to allow our TSC families to come together to talk, do crafts and eat. It was the first one since the COVID pandemic, and we had a great time! Several of our patients and their families as well as our clinic staff and colleagues attended.

Nurse Paula: We were lucky enough to host a TSC Patient and Family Fun Day this year in May. It was a wonderful way to connect with our families in a fun and relaxed environment. We were also able to provide information about clinical trials and medication and connect families to bring together the TSC community. We are hoping to make this an annual event and continue to build upon last year's momentum.

Kelly: I am often contacted by prospective allied health students about my job and participate in STEM career fairs. During these interactions I discuss my work with TSC families through our clinic as being a rewarding part of my work experience. I'm pretty observant and read people's t-shirts and often comment on them; I met our TSC Alliance Clinic Ambassador on vacation in Myrtle Beach after reading her nephew's TSC t-shirt!

Dara: I recently participated in the TSC Patient and Family Fun Day, which allowed me to help other families engage with one another to create an environment for support.

What are the most challenging aspects of your clinical work or research as it relates to those affected by TSC?

Dr. Nolan: Tuberous sclerosis complex-associated neuropsychiatric disorders (TAND) include a wide range of cognitive, behavioral and psychiatric conditions. While progress is being made, there remains a great need for new and innovative treatments. At Beaumont, we have been able to participate in various epilepsy medication trials, and I am hopeful that TAND-related clinical trials will become more widely available to our patients as well. We are also working on recruiting a Behavioral Pediatrician to our team at Beaumont who would expand access to care.

PNP Anne Marie: One of the most challenging aspects in my practice as it relates to those affected by TSC is resources. We live in such a challenging time and insurance is not covering items needed by our patients as in the past. Providing access to care as well as making sure our patients are able to obtain their medications and equipment needed in a reasonable time frame are also challenging.

Nurse Paula: I agree with Anne Marie. So much of what I do is working with insurance to get coverage for necessary medications and services. The healthcare system, in general, is very hard to navigate, so I try to be a point of contact for families who can call me directly to ask questions and receive guidance.

Kelly: Trying to make families understand they have no control over their genes and that it's not a parent's fault when they and their child are diagnosed.

Dara: The challenging aspect of my clinical work is witnessing the patients face an incurable diagnosis.

What are the most fulfilling aspects?

Dr. Nolan: One of the most fulfilling aspects of my clinical practice has been watching our young patients with TSC grow and change. I strive to always practice with a family-centered model, whether we are celebrating a successful epilepsy surgery or exploring treatment options when new seizures arise. It has been very rewarding to work with such an active patient advocate community such as the TSC Alliance.

PNP Anne Marie: One of the most fulfilling aspects of my clinical practice is developing relationships with my patients and their families and watching the children with TSC grow up. I have always practiced a family-centered care approach and providing care, problem solving with the families, and just being there for my patients and their families with TSC is very rewarding.

Nurse Paula: I enjoy being a problem solver, whether it's figuring out to get a medication covered by insurance or helping to address a new symptom. There's always a sense of satisfaction when we can help families overcome an issue, small or big. Most importantly I enjoy connecting with families and watching our TSC patients grow and thrive.

Kelly: Meeting our kids and helping celebrate their health improvements.

Dara: The most fulfilling aspect of my clinical work is to see patients achieve milestones that seemed impossible.

“There's always a sense of satisfaction when we can help families overcome an issue, small or big. Most importantly I enjoy connecting with families and watching our TSC patients grow and thrive.”

TSC is considered a linchpin disease, meaning every advance made in TSC research may benefit other more prevalent diseases like epilepsy, autism and cancer. What would be your priority if you were awarded a grant for \$1 million?

PNP Anne Marie: My priority if I were awarded a \$1 million grant would be to fund clinical research for further medical and psychosocial therapies for treating epilepsy, autism and other behavioral disorders. I think patients with TSC have so many needs and would benefit so much from further medical and psychosocial therapies to make their lives better and more manageable.

Dara: If I was awarded a grant of \$1 million to support the TSC Clinic, I would love to use some of the funding to start a support group for TSC families. This support group would meet monthly to share medical experiences, provide encouragement and have heart-to-heart conversations. This support group would have annual retreats and fairs that would help provide the patients and family with fun and relief. These are just some of the many ideas that the support group would offer.

How do you balance your time between your clinical and personal time and what do you enjoy doing outside of work?

Dr. Nolan: I am grateful to be at a hospital that encourages a good work-life balance. Most of my personal time is spent with my family including my husband, Ian, and three young children (Adeline, Benjamin and Callum). Our summer this year has been spent balancing ballet practice, swimming at the pool and welcoming baby Callum to our family!

PNP Anne Marie: I am always trying to achieve work-life balance. I enjoy my work very much and love taking care of my patients and their families. I am married and have one son. I love spending time with them and my siblings as well. I enjoy taking walks with my husband and son as well as playing outside with our Labrador. I also love to collect Hallmark ornaments, Harry Potter and Disney memorabilia and display them in my house all year round.

Nurse Paula: I am very lucky to have a wonderful and supportive husband and son (and new baby on the way!), and I enjoy relaxing with them in my free time. We love to travel, especially to our favorite spot, Mackinac Island, as often as our schedules allow.

Kelly: Fortunately, there really are no “genetic emergencies” so I have a good work-life balance. I enjoy being with my family, gardening and reading when I'm not at work. I also like to volunteer for various social issues.

Dara: I am big on the words balance and self-care. I believe in when it's time to end the workday, I leave work where it's at and don't take it home with you. Outside of work I enjoy organizing and planning events, spending time with family and simply enjoying life.

Honorariums (November 30, 2021 – August 31, 2022)

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Tribute(s) for Blake Zuther
Ms. Anna Zuther

Memorials (November 30, 2021 – August 31, 2022)

Contributions are given to the TSC Alliance at the request of family members in memory of their loved ones. We extend our sympathies to the family and friends of those memorialized below. These generous contributions support the progress of our mission to find a cure for tuberous sclerosis complex.

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