

Tuberous Sclerosis Alliance
Silver Spring, Maryland

Director of Medical Affairs

The Tuberous Sclerosis Alliance (TS Alliance) is dedicated to finding a cure for tuberous sclerosis complex (TSC) while improving the lives of those affected. Tuberous sclerosis complex is a genetic disorder that causes tumors to form on vital organs and is the leading genetic cause of epilepsy and autism. We are the only organization able to rally the financial resources, the research, the partnerships, and the sheer will of TSC-affected families and individuals to break the back of this "linchpin" disease. With an annual budget of \$5.7 million, we concentrate our resources on research as well as information and advocacy to individuals and families living with TSC.

The TS Alliance will mobilize the resources to drive scientific breakthroughs for treatment and preventative therapies for TSC, advocate for appropriate access to care and provide community services that improve the quality of life for those affected by TSC in the United States and around the globe.

- Accelerate scientific advancements by funding research; driving the growth of tools and consortia that support basic, translational and clinical research; and advocating for federal and state research funding by partnering with government, industry sponsors and other patient organizations.
- Engage and help more individuals impacted by TSC through improved clinical and support services.
- Empower our grassroots community to broaden and strengthen the base of financial support from private and public sources for TSC research, the TS Alliance and the TS Alliance Endowment Fund.
- Drive and provide tools to facilitate peer to peer support among the national and international TSC community.
- Increase diversity of Board membership and enhance staff skill sets to ensure execution of the strategic plan and to maintain recognition of TSC as a linchpin disorder.
- Develop and implement strategies to navigate TSC patient care, advocacy, outreach, funding, and research during the COVID-19 pandemic.

The TS Alliance's research strategy focuses on driving collaborative science through five programs: Research Grants, Natural History Database, Biosample Repository, Preclinical Consortium, and Clinical Research Consortium. Clinical Research Consortium investigators have been awarded more than \$35 million by the National Institutes of Health (NIH) through competitive grant processes. TS Alliance personnel serve on the leadership team for the Consortium, actively track enrollment, and raise community awareness to help identify potential participants for clinical studies. The TSC Biosample Repository collects biosamples such as blood and tissue that are linked to clinical data in the TSC Natural History Database, including biosamples from ongoing clinical studies in the Clinical Research Consortium. These samples and clinical data are available to researchers worldwide to study disease processes in TSC. Additionally, the TS Alliance recognizes TSC Clinics and TSC Centers of Excellence as a resource for the TSC community to identify where comprehensive clinical care for people with TSC is available, including institutions in the United States and countries represented by our Global Alliance partners.

Reporting to the Chief Scientific Officer (CSO), the Director of Medical Affairs (DMA) is a new, hands-on position working closely with the Director of Clinical Projects and TSC Clinic Liaison to provide information and assistance to constituents needing help accessing clinical care for TSC and FDA-approved treatments. Toward this goal, the DMA will lead development of a

new web-based TSC Navigator tool to help individuals and families navigate the complex TSC healthcare system and proactively manage their care. Over the next few years, the DMA will drive implementation of a TSC Learning Healthcare System working closely with TSC Clinic directors, staff, and community partners. The DMA will be an important contributor to research projects within the Science and Medical Department including the TSC Clinical Research Consortium, Innovation Workshops, and international research conferences. The role requires communication and collaboration with a broad range of stakeholders, including TSC community members, all TS Alliance departments, academic and industry medical professionals, healthcare professionals, industry partners, specialty pharmacies, payors and government agencies such as NIH, CDC, and FDA.

This position will be full-time and based in the TS Alliance office in Silver Spring, Maryland, although working from another location may be considered if the ideal candidate cannot relocate to the metropolitan DC area. Occasional travel will be required to participate in relevant TS Alliance meetings and educational or scientific conferences.

ORGANIZATIONAL STRUCTURE AND INTERFACES

Reports to: Chief Scientific Officer (CSO)

Primary Interfaces (internal): CSO; President and CEO; Director, Clinical Projects and TSC Clinic Liaison; VP, Community Programs; Manager, Community Programs East/West; SVP, Communications Strategy; Associate Director, Research; Science Project Coordinator; Director, Preclinical Research

Primary Interfaces (external): TSC Clinic Directors, nurses, and research coordinators; individuals living with TSC and their families; clinical researchers in academia and industry; patient access partners at specialty pharmacies; payors; Professional Advisory Board members; Clinic Ambassadors and other TSC Connect volunteers; Board of Directors

MAJOR FUNCTIONS

- Act as first point of contact for newly diagnosed families and those seeking guidance on new manifestations of TSC.
- Lead the design and implementation of TSC Navigator and TSC Learning Healthcare System.
- Develop both long- and short-range strategic and operational plans to strengthen and grow the TS Alliance's clinical programs.
- Serve as liaison to the Clinical Research Consortium, offering the patient voice in clinical trial design, recruitment and education

RESPONSIBILITIES

Provide accurate, up-to-date health information, support for access to care and medication, and advocacy services to TSC constituents via TSC Navigator, telephone, email, Zoom, social media and one on one interactions:

- Develop and grow the web-based TSC Navigator tool to help individuals and families navigate the complex TSC healthcare system.
- Through the TSC Navigator, increase partnerships with specialty pharmacies, payors, industry, patient assistance programs, and private foundations to help ensure access to FDA-approved treatments.
- Develop and provide educational materials to the constituency to empower them to secure services including medical and psychosocial care, treatment for the manifestations of TSC and information on state/ federal regulations affecting persons with disabilities through the TS Alliance partnership with The ARC.

- Facilitate linkages to community resources including, but not limited to volunteer programs, online communities, social service agencies, medical service providers, and information centers and other supporting organizations.
- Provide crisis intervention referrals as appropriate.
- Share responsibility for addressing urgent constituent concerns such as medication access, including nights and weekends.

Expand knowledge of evidence-based, best practices of TSC clinical care among TSC Clinic healthcare professionals and other medical providers involved in the treatment of TSC:

- Ensure all TSC Clinics are aware of and implementing the latest guidelines for surveillance and management of TSC as stated in TSC Clinic standards approved by the Board of Directors.
- Develop bi-annual curriculum (e.g. CME/CNE or TSC workshops at professional association meetings) that exposes TSC Clinic Directors and other health care providers to current evidence-based practices for TSC diagnosis, surveillance, and management.
- Create “TSC Net” to expand access to care for people in regions with no TSC Clinic or TSC-knowledgeable healthcare professionals and to improve access and delivery of evidence-based, high quality clinical care for patients with TSC, including comprehensive adult care for inpatient and outpatient services.
- Oversee relationships with Professional Advisory Board for questions by healthcare professionals on medical topics not addressed by consensus guidelines

Contribute insight and advice to the TSC Clinical Research Consortium:

- Serve as a resource to TSC Clinic Research Consortium and study coordinators.
- Ensure the patient voice is represented in development and review of clinical study protocols.
- Educate the TSC community about current clinical trials.

Implement Learning Healthcare Systems:

- Serve as TS Alliance liaison to the Epilepsy Learning Healthcare System.
- Develop a plan to implement a TSC Learning Healthcare System in 2023-2025.

Other Duties:

- Provide original articles and resource information for the TS Alliance magazine, *Perspective*.
- Provide monthly activity reports to the CEO and CFO for inclusion in the monthly report to the Board of Directors and Monthly Balanced Scorecard.
- Limited travel required, including nights and weekends
- Other duties as assigned.

CORE VALUES

Build Value-Based Relationships: Generating alliances internally and externally by continuously identifying and acting on those things that will create success for the organization and its constituents, researchers, health care professionals and communities.

Contribute to Team Success: Actively participating as a committed member of a team and working with other team members to help complete goals and deliverables.

Customer Focus: Making customers (external and internal) and their needs a primary focus of one's actions; developing and sustaining productive relationships; creating and executing plans and solutions in collaboration with team members internally and externally.

Provide Feedback: Objectively observing, analyzing, and sharing perception of other people's performance to help reinforce or redirect behavior to improve performance and results and providing feedback that is timely, specific, behavioral, balanced, and constructive.

Work Standards: Setting high standards of performance for self; assuming responsibility and accountability for successfully completing assignments or tasks; self-imposing standards of excellence rather than having standards imposed.

Consult: Providing timely, specific information, guidance, and recommendations to help volunteers, Community Alliances, and fellow staff members make informed committed decisions that will lead to sustainable impact.

Establish Collaborative Working Relationships: Developing and using collaborative relationships to accomplish work objectives; developing relationships with other individuals by listening, sharing ideas, and appreciating others' efforts.

QUALIFICATIONS

- Bachelor's degree in nursing (BSN) or closely related field with at least ten years of experience in clinical care and/or clinical research required.
- Experience working with payors and specialty pharmacies desired.
- Previous experience involving clinical care or research on TSC or related disorders desired.
- Ability to work well both face-to-face and remotely with people at all educational levels required.
- Demonstrated ability to drive forward multiple projects simultaneously required.
- Excellent oral and written communication skills required.
- Experience translating and communicating complex medical information in lay terms desired.
- Skill to function under deadlines, strong critical thinking, organizational skills, and attention to detail required.
- Proficiency in MS Office (Word, Excel, PowerPoint, Outlook) desired.