

**TSC Alliance**  
**Global Relations Committee Notes**  
**October 13, 2023**  
**Approved: January 9, 2024**

**In attendance**

**Committee Members (Voting):** Darcy Krueger (Chair), Kristi Lengyel\*, Laura Marks, Mustafa Sahin\*

**Non-Voting Committee Members:** Andrew Duffy (International Partner Member)

**Non-Committee Board Members (Non-Voting):** Derek Bauer, Matt Bolger, Rob Grandia, Dana Holinka, Jonathan Goldstein, Bill Joseph, Sean Shillinger

**Other Guests (Non-Voting):** Danielle Clark, Frances Harper, Mark Keezer\*

**Staff:** Ayat Abi, Liz Cassidy, Zoë Fuchs\*, Jaye Isham, Maddison Larrimore, Steve Roberds, Kari Rosbeck, Katie Smith

*\*Denotes participation by Zoom*

Darcy Krueger confirmed a quorum and called the meeting to order at 8:36 am ET.

**Review and Vote on Committee Meeting Minutes from March 2, 2023**

Marks motioned to approve the minutes from the March 2, 2023 Global Relations Committee meeting. Sahin seconded the motion. *The motion was approved without dissent.*

**Updates on International Activities of the TSC Alliance/Global Relations Committee**

*Other Business*

Other business regarding the situation in Israel and Palestine was discussed at the beginning of the meeting. The TSC Alliance received a few inquiries about whether the TSC Alliance would put out a statement on the conflict in support of Israel. We have been in contact with several members of the TSC Alliance of Israel and all the TSC Clinic Directors and are currently watching the situation closely. Feedback from the TSC Alliance of Israel thus far is that there is a need for iPads to entertain the children.

When the situation in Ukraine arose last year, we were able to provide assistance with issues around medication access. As we are a patient advocacy organization, the Committee decided a statement around the conflict was outside our scope. If we get additional inquiries on how to help, we can address them on an individual basis and direct people to the TSC Alliance of Israel website but will not make a broad statement.

*Updates*

The TSC Alliance continues to serve as the coordinating hub for TSCi. The 2023 TSCi Workshop took place September 6-7 in conjunction with the 2023 International TSC Research Conference. 40 participants joined the workshop from 21 countries. The workshop included updates from each country's representative, a panel discussion on international investigator-driven and industry-led clinical trials and how to work better together as well as an update on TANDem and the TAND toolkit.

The Natural History Database (NHD) is being piloted globally in Canada. We are in discussion with both Mexico and India about giving them a copy of the NHD for their countries. They would be responsible for the data entry and maintenance of the NHD, and it will be important each country's privacy laws are followed. After the database in Mexico and India is launched, we could explore the possibility of non-Global Alliance countries participating. We are also working with several TOSCA investigators on getting access to that database and importing it into the NHD.

We continue outreach in low- and middle-income countries and partnered with Pretola again this year on a clinician education session on TSC.

The TSC Alliance will be hosting the TSC Canada and TSC Alliance of Mexico web pages when the redesigned website launches in January 2024.

### **Global Alliance TSC Clinic Recognition Process**

In the past the Global Alliance TSC Clinic applications have been reviewed and approved by the Science and Medical Committee. It has been difficult to apply the US clinic framework to non-US healthcare delivery systems. We are also working to build TSC expertise in our Global Alliance countries. Primary updates to the process include a letter of support from the Global Alliance to apply for Global Alliance TSC Clinic recognition, a Zoom meeting with the TSC Clinic Director, and the applications will now be reviewed and approved by the Global Relations Committee before being voted on by the full board. Global Alliances can help with recruiting and engaging clinicians in their countries. We can look for ways to partner with the clinics; for example, we are working with TS Canada and Drs. Keezer and Major on a webinar about their clinic and involvement in the Natural History Database and Biosample Repository.

### **Review Strategic Plan for Global Relations 2024-2029**

Foster international relationships and development of resources to better serve the worldwide TSC community:

- Grow global clinics from 13 to 25 by 2028.
- Work with TSCi to increase the number of countries participating in TSC clinical trials by 25% by 2028
- Foster partnerships in 10 low- or middle-income countries with no association representation by 2028.

### **Review and Vote on 2024 Global Relations Goals**

1. Grow depth and value of relationships with global partners through the development of country-specific strategic plans, helping increase each country's constituencies by 5% from baseline and increasing the number of globally recognized TSC Clinics to 18 in 2024.
  - a. Grow the existing Global Alliances by helping develop regional and country-specific needs.
    - i. Support country and regional conferences in Global Alliance countries.
    - ii. Support country and regional webinars in Global Alliance countries.
    - iii. Partner with international organizations on clinician outreach and education.
  - b. Identify and cultivate two new Global Alliance prospects.
    - i. Explore continental and regional hub models leveraging existing Global Alliances and/or TSCi Member Associations.
    - ii. Develop a sustainable model for partnering with low- and middle-income countries.
2. Ensure proper agreements and financial reporting are in place for TSC Alliance Global Alliances, including clarification of new TSC Alliance branding/logos/name use, etc.
3. Secure future funding support for both the Global Alliance program and TSC International (TSCi).
4. Serve as the coordinating center for TSCi activities, including website maintenance and the inclusion of an educational information portal, TSC Global Awareness Day on May 15 and physician education about the International Clinical Consensus Guidelines.
  - a. Ensure global representation in person or virtually from TSCi members and additional countries in TSCi activities and initiatives.

- b. Support research and access to clinical care in TSC globally (ex. NHD/registries, care delivery, implementation of the guidelines, access to medicines, online resources for locating TSC expertise, etc.).
- c. Work with TANDem Consortium to promote TAND toolkit and resources and to validate TAND SQ.
- d. Leverage existing accomplishments with the UN, WHO, RDI and similar organizations to advance TSC care and access worldwide.
- e. With TSCi, work to build a global network for clinical trials.

Based on the conversation with the committee, goal 5 was added to the 2024 Global Relations Committee Goals.

- 5. Assess the needs and develop a strategy for supporting TSC patients, families, clinicians, and regulators where there is no existing TSC infrastructure.
  - a. Reach out to international organizations including ICNA, ILAE, RDI, NORD, and rare disease organizations in countries and identify programs and resources in place that we can contribute to
  - b. Identify TSC experts already engaged in outreach in countries without TSC representation.

*Marks* moved to approve the 2024 Global Relations Committee goals with the addition of goal 5. *Lengyel* seconded.

#### **Other Business and Adjourn**

The next Global Relations Committee meeting will be scheduled for January to discuss additional ways we can raise global awareness and increase outreach around the 2024 Global Relations Committee goals.

With no further business, *Lengyel* motioned to adjourn the meeting. *Marks* seconded. The meeting adjourned at 9:59 am ET.

Respectfully submitted,

Katie Smith  
Director, Government and Global Affairs