Consortium FAQs

The Q&A below addresses general questions about the CureSHANK Biomarkers and Outcome Measures Consortium. We hope you will find this informative. Companies who are interested in joining the Consortium agree to a Term Sheet that provides details on participating in the Consortium, roles and responsibilities, policies, goals, operation, funding, and establishing success measures for consortium projects.

Q: Why is the Consortium is being developed?
A: CureSHANK held a Consortium Launch Meeting in April where we discussed the need to come together to advance biomarkers and outcome measures in Phelan-McDermid Syndrome. **The recording of the launch meeting is here**: https://www.youtube.com/watch?v=QgXrPhZKZ_8
The Consortium mission and goals are also detailed in the Consortium Term Sheet for participation.

Q: How is the Steering Committee different from Affiliates?
A: **Consortium Members are companies who pay a Membership fee** for full participation. All companies who pay a membership fee are represented on the Steering Committee and may participate in Projects. **Affiliates are not Members** and are not represented on the Steering Committee. Affiliates pay a fee to attend an annual meeting for informational purposes.

Q: Are companies advisors? Can companies participate in the Executive Committee or the Steering Committee?
A: **Companies are not advisors,** companies are Consortium Members. Consortium Members serve on the Steering Committee. **The Executive Committee is composed of CureSHANK and its advisors.** The Consortium Term Sheet defines advisors, members, project teams, affiliates, etc. and includes a detailed description of the Governance Structure.

Q: How will the Consortium be funded?
A: The Consortium **will be funded mainly through company Membership fees and project funding** as well as fundraising efforts by CureSHANK. There will be a budget process whereby the budget will be reviewed by the Steering Committee and recommendations made to the Executive Committee and the EC will approve the budget. Membership fees will be evaluated annually.

Q: Is the Membership fee annual or per project?
A: The **Membership fee** for companies is **annual**. All companies pay the same membership fee. The membership fee will allow for fair participation among all members and will be reviewed annually against the Consortium financials. **Projects will have their own budget** depending on the details of the work proposed. The Consortium Term Sheet provides further details.

Q: From a project perspective how will the different companies be able to work together?
A: The Consortium establishes yearly goals, the Steering Committee discusses proposed projects and makes recommendations to the Executive Committee. **Any Consortium Member can propose a project and any Consortium Member can work on a project.** There will be a formal process to submit project plans for consideration. The EC reviews project plans and funding plans associated with the projects and once a project is approved, a Project Team is formed, commences work, and the Steering Committee oversees the Project Team. The aim is to provide a pre-competitive space where the work we accomplish benefits all companies and the field as a whole.

Q: How will academic experts or clinicians participate in the Consortium, as bringing their view to the Steering Committee may be beneficial?
A: The Steering Committee is composed of **only companies**. The aim of this structure is to provide opportunities for all companies to benefit from working together on projects that advance biomarkers and outcome measures. **It is important to have subject matter expertise available and regular updates from academicians and clinicians**, and that will take many forms, to include advisors to the Executive Committee and the Consortium as a whole, presentations from key opinion leaders, and relevant project work participation.

Q: What is the anticipated time commitment for Consortium meetings?
A: We anticipate **quarterly** remote meetings. The Steering Committee may, however, recommend holding an in-person meeting.

Q: Will there be regulatory engagement on projects/plans?
A: Project plans will include any relevant regulatory input or considerations and propose engagement **as appropriate.**

Q: How will Consortium Members be able to leverage data or tools developed through the Consortium?
A: The Consortium will have operational procedures, financial accountability, and **policies for data sharing, intellectual property, confidentiality and conflict of interest**. The Consortium Term Sheet details Consortium operations, policies and procedures.