



## Governance Elements

PACT is a pre-competitive collaboration organized to gather and analyze data & information that informs and educates industry-wide use of decentralized clinical trial solutions and their associated performance, quality and economic outcomes.

- Each company agrees to actively participate in discussions and to collect/ contribute data according to the consensus-based sampling frame and data collection plan:
- Initially, data collection will be conducted using Excel worksheets; eventually, the Consortium intends to move to a cloud-based data collection platform
- For those companies unable to use the cloud-based platform, Tufts CSDD will develop a custom approach to entering the data from the worksheets into the platform
- For issues requiring a vote: Each company appoints a representative and a simple majority (>50%) vote addresses/resolves the issue, i.e. each participant has a 'board seat'
- No individual participating company will ever be identified in the benchmark data. Only, de-identified, overall and subgroup aggregate data will be presented
- On an ongoing basis, Consortium members will actively solicit input from investigative sites, service providers and patients/ patient advocates. The Tufts CSDD team will act as a central coordinating function
- A member company may choose to end its participation at any time; the data provided by that company prior to the end of participation will remain with the Consortium and may be used in the benchmark analyses. That company's data will be de-identified and only presented in the aggregate
- The Consortium has received funding to cover year one operating expenses from the Regan Udall Foundation for the FDA and from Medable. In year two and beyond, support for PACT will come from participating member companies and from other sponsorship sources.