

Thank you for your interest in the Predictive Safety Testing Consortium (PSTC)! This exciting public-private partnership operates under a unique legal agreement that brings members together to share resources and expertise toward the goal of qualifying new safety biomarkers for preclinical and clinical safety assessment. Our current areas of focus cover nephrotoxicity, hepatotoxicity, vascular injury, non-genotoxic carcinogenicity, and skeletal muscle and cardiac hypertrophy. Regulatory agencies and academic colleagues participate as advisors and Critical Path Institute acts as a third party, partner, project manager, and project catalyst.

If you have an exciting technology, assay, or service that you believe the PSTC would be interested in, we would be delighted to be informed. However, the process for vetting such technology is not directly through Critical Path Institute, but rather via sponsorship through a member. Since our membership includes Abbott; Amgen Inc.; AstraZeneca Pharmaceuticals LP; Boehringer Ingelheim Pharmaceuticals, Inc.; Bristol-Myers Squibb Company; ClinXus; Daiichi Sankyo; Eli Lilly and Company; GlaxoSmithKline; Johnson & Johnson Pharmaceutical Research & Development, LLC; Merck and Co., Inc.; Mitsubishi Tanabe Pharmaceutical Corporation; Novartis Pharmaceutical Corporation; Pfizer, Inc.; Roche Palo Alto, LLC; and sanofi-aventis U.S., Inc., it is likely that you already have a business relationship with a member. The next step would be to ask your contact in that company to present data they have developed with your technology or assay to the appropriate PSTC Working Group.

There is also a role for “non-member participants” in the PSTC. Non-member participants could include a wide range of different types of organizations such as service companies that the project teams choose to contract with, and/or non-profit organizations that have something substantial to contribute but may not meet the Membership Criteria. It should be noted that such participants do not have the full privileges and responsibilities of full members; thus, invited participants do not have a vote in defining strategy nor do they have broad access to Working Group confidential information. A member company may propose that an individual or organization participate with a Working Group through signing a Confidentiality Agreement, allowing the individual or organization to exchange specific information with the Consortium. In addition, a Non-Member individual or organization may enter into a Project Agreement with a Consortium Project Team. This arrangement will specifically cover legal issues such as Material Transfer and allow the Non-Member to participate in the research activities of the Project Team.

Full membership in the Predictive Safety Testing Consortium should not be considered lightly, as the expectation is that members will substantially contribute of their own resources to the goals of the Consortium, and participate in a number of Working Groups.

Criteria for membership may be briefly listed as:

1. The proposed Member must be engaged in the research, development, or regulation of pharmaceutical products and fall within one of the following categories:
  - a. governmental agency
  - b. non-profit research institution; or
  - c. pharmaceutical or biotechnology company
2. The proposed Member must satisfy either (a) or (b) below:
  - a. The proposed Member has both: (i) the willingness and ability to contribute one or more nominated exploratory Safety Biomarkers, other useful information, and/or materials for use in Consortium research activities; and (ii) the capability to cross-validate Safety Biomarkers; OR
  - b. The proposed Member is willing and able to conduct substantive experiments directed toward, and dedicate meaningful resources to, cross-validation of one or more nominated Safety Biomarkers, and the specific capabilities and resources of the proposed Member would fill an existing or reasonably foreseeable and currently unmet need of the Consortium in its efforts to expeditiously achieve the objective of the Research Program.
3. The proposed Member must be willing to execute the Consortium Agreement in its current form and to abide by its obligations thereunder.

For more information, or to pursue an interest in PSTC Membership, please contact Dr. Elizabeth Walker, Director, PSTC at 520-547-3440.

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