

## Procedures for Initiating Collaborative Research Projects

The UCSF-Stanford CERSI aims to meet scientific challenges in issues of critical importance in the development and evaluation of FDA-regulated products and at a time of rapid technological progress by:

- Advancing regulatory science through the development and application of quantitative and systems-level methodologies.
- Creating a West Coast presence of the FDA to enhance communication between academia and the pharmaceutical, biotechnology, and high-tech industries, with the FDA, about regulatory science.

Although all collaborative research projects are of potential interest, our center has a focus on data science and precision medicine.

We are gratified at the great interest shown in establishing collaborative research projects with the UCSF-Stanford CERSI, and in the interest of a transparent process, provide these guidelines in order to set expectations about how to establish collaborative research projects. In general, there are key ingredients required for a collaborative research project to be approved by the UCSF-Stanford CERSI.

1. The collaborative research project should have a **strong scientific rationale**, consistent with the theme of regulatory science: it should be seeking new knowledge that will be directly useful to developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.
2. The collaborative research project should have **identified FDA scientists** who would work with scientists from UCSF-Stanford and, in some cases, from industry to advance the goals of the project. This ensures that work is relevant to the FDA mission, and can be integrated into workflows if successful.
3. The collaborative research project should have **identified UCSF and/or Stanford scientists** who are willing to take the academic lead on the project, manage the milestones, budget and deliverables, consistent with their interests and expertise. Selection of UCSF and/or Stanford scientist collaborators who are members of the UCSF-Stanford CERSI is preferred, see: (<https://pharm.ucsf.edu/cersi/people>) for a list of UCSF-Stanford CERSI scientist members with area(s) of expertise. However, any scientist at UCSF and/or Stanford may be selected.
4. **Optionally**, the collaborative research project can have **identified industrial partners** who bring expertise and resources to the project, consistent with the rules of UCSF, Stanford and FDA on conflict of interest, intellectual property and other relevant guidelines.
5. The collaborative research project should identify the proposed **source of financial support** for academic, FDA and (optionally) industrial participants. The UCSF-Stanford CERSI has very

limited funds for seeding projects. Sometimes, the FDA is able to flow incremental funds for meritorious projects through its component centers or through overarching Broad Agency Announcements (BAAs). Collaborative research project advocates should investigate sources of funding, working with CERSI leadership.

The leadership of the UCSF-Stanford CERSI in general can offer advice and direction in assembling these ingredients, but are unable to broker collaborations between academics, FDA and industry, and so those relationships should be established by the collaborative research project advocates. Similarly, the CERSI has a small amount of funds to seed collaborative research projects, and will be able to give some indication of the availability of such funds to start collaborative research projects. Finally, it should be understood that the UCSF-Stanford CERSI leadership must prioritize their efforts to push collaborative research projects most consistent with the focus of the CERSI.