DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Request for CDER Participation in a Public Private Partnership (PPP) or Consortium Activity

PPP Name or Title	Coordinating Organization Name

Contact information of the Executive Officer or Official Representative for the PPP or Consortium

Name	Title
Email	PPP or Consortium Website

PPP or Consortium Mission.

Public health need(s) that the PPP or Consortium activities seeks to address.

Provide a list of member or stakeholder organizations.

Provide a description of the PPP or consortium governance plan. Include stakeholders involved, funding mechanism, and membership rules (attach relevant documentation, if available).

Describe information about the types of activities (e.g. a project working group, scientific steering committee, etc.) for which you are requesting participation by a CDER PPP Liaison. Include a list of any additional working groups or projects.

What are the anticipated duration and frequency of CDER's participation in the activities? Indicate whether in-person meetings or virtual meetings are involved, and whether the meetings are open to the public.

What are the potential outcomes/deliverables of the activities?

Describe a brief plan for providing regular public updates *(e.g., via a website)*, including new projects, outcomes, work products and reports associated with the activities.

Have you discussed this request with a CDER employee? ◯ Yes ◯ No

Provide the name of the CDER employee

The Coordinating Organization agrees to the following assurances:

- Any membership or registration fees required for participation in the PPP activities will be directly related to the costs of the activities.
- The activities and scientific publications will be based on sound scientific evidence and will promote the development of new tools to facilitate innovation, improve medical product development and advance public health.
- The Coordinating Organization will not mislead interested parties by suggesting in written or oral promotion that: (1) industry funds or fees will pay for access to or influence on FDA or (2) FDA endorses the Coordinating Organization, activities of any PPP participants, or particular products.
- The Coordinating Organization understands and agrees to comply with the conditions imposed by federal ethics rules on FDA participants, including conditions on the acceptance of gifts, honoraria, travel reimbursement, and prospective employment.
- The Coordinating Organization will publicly disseminate the outcomes and proceedings of working groups, workshops, and scientific meetings.
- The Coordinating Organization will post regular public updates, including new projects, outcomes, work products and reports associated with the activity.
- The Coordinating Organization will allow FDA an opportunity to review press release to review and provide comments on any press releases.

Name of Authorized Coordinating Organization Official	Title of Authorized Coordinating Organization Officer

Signature of Coordinating Organization's Authorized Official	Date