U.S. FOOD & DRUG ADMINISTRATION

Critical Path Innovation Meeting (CPIM) Request Form

Requester's Name:

Name of Organization:

Type of Organization:

Briefly describe the organization you represent:

Is your organization planning to, or currently involved in any of the following activities with the FDA?

Regulatory Submission (i.e. Pre-IND, IND, NDA, BLA, etc.)

- ◯ Yes
- ◯ No

Application/Reference Number, if applicable:

Drug Development Tool (DDT) Qualification Submission (i.e. Clinical Outcome Assessment (COA), Biomarker)

- ◯ Yes
- ◯ No

Application/Reference Number, if applicable:

Brief description of the DDT proposal (i.e. concept of use, or context of use)

Please indicate if your organization is engaged in any other activities with the FDA. (i.e. external stakeholder meeting, Model Informed Drug Development program, etc.)

Preferred format of the CPIM:

Briefly state the purpose of the meeting request, desired outcomes and steps you have taken toward your goal.

To help evaluate this request, please list up to 4 specific questions you have for the FDA. These questions should help guide the discussion at the meeting.

If you have any additional information, you may attach a document no longer than 6 pages here. Attachment

SUBMIT