POLICY AND PROCEDURES

Office of Translational Sciences

Critical Path Innovation Meetings

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PURPOSE

The purpose of this MAPP is to delineate the roles and responsibilities of CDER staff and outline the procedures to be followed for a Critical Path Innovation Meeting (CPIM).

BACKGROUND

A CPIM is a nonbinding scientific dialog between FDA and investigators from industry, academia, patient advocacy groups, and/or other government agencies to explore novel ideas with the potential to augment drug development and advance regulatory science and policy.[1] A CPIM is a forum for the general discussion of challenges in drug development — as well as innovative strategies to address them — and is not specific to any particular medical product. The CPIM is not intended to replace discussions with review divisions on drug-specific development efforts.

[1] See reference 1, guidance for industry *Critical Path Innovation Meetings* (April 2015).

The scope of the CPIM includes but is not limited to:

- Drug Development Tools, including biomarkers and clinical outcome assessments (COAs) in the early phases of development that are not yet ready for Drug Development Tool Qualification Programs[2]
- Natural history study designs and implementation
- Emerging technologies or new uses of existing technologies
- Innovative conceptual approaches to clinical trial design and analysis
- Patient-, Clinician-, and Observer-Reported Outcomes Assessments

A CPIM is not a:

- Substitute for formal pre-IND, IND, NDA, BLA, or other regulatory meetings
- Venue for organizations to market commercial products to or seek endorsement from the FDA
- Forum for organizations to obtain FDA's detailed review and analysis of data

Potential outcomes of CPIMs include the initiation of actions leading to:

- Regulatory submissions of clinical trials with new designs and methods
- Proposals for the use of emerging technologies
- Proposals for biomarker qualification or the use of biomarkers in regulatory submissions
- Natural history studies
- Public workshops and future collaborations between FDA and external parties
- Development of new guidance
- Formation of new consortia and public-private partnerships to advance regulatory science efforts

POLICY

- The CPIM program is administered by the Office of Translational Sciences, Immediate Office (OTS-IO).
- Evaluation of materials for and participation in a CPIM is conducted by FDA subject matter experts (SMEs) and is voluntary and dependent on resources.
- A CPIM is a general discussion that does not involve the detailed evaluation of data.
- A CPIM does not include any discussion of individual drug development programs.

[2] See reference 2, Guidance for industry and FDA staff *Qualification Process for Drug Development Tools* (November 2020).

- To the best of their knowledge, CDER and other FDA participants' perspectives during the meeting will be consistent with CDER and FDA policy. Their individual perspectives should not be treated as necessarily describing established policy.
- CPIM discussions and meeting summaries are nonbinding.

RESPONSIBILITIES

CPIM Project Manager (PM)

- Notifies the CPIM Scientific Lead (SL) of CPIM requests.
- Serves as the point of contact with the Requester and participating FDA centers, offices, and divisions for administrative issues and the transfer of documents.
- Communicates with the CPIM Requester as needed to refine and clarify the nature of a CPIM request.
- Directs the Requester to an appropriate FDA center, office, division, or other FDA venue if the topics are not appropriate for a CPIM.
- Manages monthly updates of CPIM data to the CPIM Dashboard.

Documentation Lead (DL)

- Conducts the initial scientific/regulatory assessment and oversees documentation.
- Takes notes during CPIM sessions and drafts the CPIM meeting summary using the standard template for review by the CPIM SL and FDA attendees.

CPIM Scientific Lead (SL)

- Appointed by OTS-IO to provide scientific leadership to the CPIM program.
- Provides scientific oversight and chairs CPIM discussions.
- Evaluates whether a CPIM is an appropriate venue for the issue or topics raised by the Requester and suggests other FDA venues when topics are not appropriate for a CPIM.
- Chairs the CPIM pre-meeting and CPIM
- Reviews and provides contributions to the CPIM meeting summary.

Subject Matter Experts (SMEs) within FDA Centers, Offices, and Divisions

- Review requests for scientific and regulatory appropriateness.
- Identify appropriate staff to participate in specific CPIMs and participate in the pre-CPIM meetings and CPIMs as resources permit.
- Edit and comment on the draft meeting summary.
- There is no expectation that FDA staff will provide written responses or evaluate materials other than the meeting materials.

CDER Center Director or Designee

- Grants final approval, denial, conditional approval, or redirect decision regarding CPIM requests.

Requester

- Submits the CPIM request form.
- Submits the CPIM preparation package at least 4 weeks in advance of the CPIM. The package should include the following:
  - Agenda
  - Proposed Attendees
  - Objectives
  - Specific questions for the FDA to consider

PROCEDURES

Submission and evaluation of request for CPIM

The Requester completes and submits the CPIM Request Form available on the CPIM web page.[3,4] This form is directed automatically to the email account CPIMInquiries@fda.hhs.gov.

- The CPIM PM will confirm receipt of all CPIM requests.
- Requests referred from other offices or divisions will be directed to the CPIM PM.
- The DL conducts an initial scientific/regulatory assessment.
- Each request received will be forwarded to the CPIM SL.
- The CPIM SL will determine if the request is within the scope of the CPIM.
- In some cases, the CPIM program may discuss modifications to the request and resubmission with the Requester.

Granting or denying a CPIM

- The CPIM PM will notify the Requester if the CPIM request has been granted.
- If a request for a CPIM is not appropriate, the CPIM SL will discuss this with the Requester and suggest other potential avenues to address the Requester's needs. The CPIM PM will connect the Requester to the appropriate centers/offices/divisions.

Arranging a CPIM

- The CPIM PM will request an information package from the Requester no later than 4 weeks prior to the CPIM.
- The information package should include a list of proposed attendees, an agenda, objectives, a presentation, any additional background information for the topic to be discussed, and specific questions for FDA to consider.

[3] See reference 3, CPIM Request Form.
[4] See reference 4, CPIM web page.

- Once the information package is received, the CPIM PM will distribute the materials to all proposed participants.

CPIM Activities

- An internal pre-CPIM meeting for the planned FDA participants is scheduled after the meeting package has been received and will be held within 30 days of the scheduled CPIM. The intent of the pre-meeting is to review the meeting materials and discuss FDA participants' perspectives on the meeting topic and requester's questions.
- The CPIM follows a structured agenda covering presentation, discussion, and closing remarks, facilitated by the CPIM SL.
- The DL drafts the meeting summary using a standard template. The CPIM SL and FDA attendees review the draft.
- The final summary will be sent to the Requester.
- Following the CPIM, the FDA website is updated with the meeting topic and date.

Records Management

All CPIM records — including request forms, meeting materials, summaries, and correspondences — must be retained in accordance with FDA records retention policies and National Archives and Records Administration (NARA) guidance.

File Code	Records Description and Authorized Disposition	NARA Approved Citation
FDA-8510	**Substantial Material.** Background materials relating to significant records, briefings for the Commissioner, external briefings, speeches, and other types of materials with long-term value. **Disposition: TEMPORARY. Media neutral**. Cut off at end of calendar year in which associated project or case is completed. Maintain a minimum of 3 years then destroy 6 years after cutoff or when no longer needed for reference, whichever is sooner.	N1-088-06-3

File Code	Records Description and Authorized Disposition	NARA Approved Citation
FDA-8510	OTS will maintain an archive of all CPIM records in accordance with NARA guidance. Records include: CPIM Request forms, summaries, SOPs, Guidance documents, MAPPs, and meeting materials stored in the Enterprise Content Management System).	N1-088-06-3

REFERENCES

1. Guidance for industry *Critical Path Innovation Meetings* (April 2015). Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/critical-path-innovation-meetings.
2. Guidance for industry and FDA staff *Qualification Process for Drug Development Tools* (November 2020). Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/qualification-process-drug-development-tools-guidance-industry-and-fda-staff.
3. CPIM Request Form. Available at: https://www.fda.gov/media/155362/download?attachment.
4. CPIM web page. Available at: https://www.fda.gov/drugs/novel-drug-approvals-fda/critical-path-innovation-meetings-cpim.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
4/15/2021	1.0	Updated records management information.
11/17/2026	2.0	Updated CPIM roles and responsibilities and returned the section to a bulleted list format. Returned procedures to sequential bulleted list format and removed detailed phase timelines. Updated the CPIM preparation package

		deadline from 2 weeks to 4 weeks prior to the CPIM. Clarified records management language and updated CPIM request/program links.