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**POLICY AND PROCEDURES**

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**Office of Translational Sciences**

**Critical Path Innovation Meetings Policy and Procedures**

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**PURPOSE**

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

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**BACKGROUND**

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

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

- Biomarkers in the early phase of their development that are not yet ready for the Biomarker Qualification Program
- Clinical outcome assessments in the early phase of development and not yet ready for the Clinical Outcome Assessment Qualification Program
- Natural history study designs and implementation

- Emerging technologies, or new uses of existing technologies
- Innovative conceptual approaches to clinical trial design and analysis

Certain issues are not in the scope of the CPIM. These include:

- Animal models used for product approval under the Animal Rule
- Numerical and computational models of human disease

Potential outcomes of CPIMs include efforts 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 collaboration of FDA with external parties
  - Development of new guidance
  - Formation of new consortia and public-private partnerships to advance regulatory science efforts
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## **POLICY**

- The CPIM program is administered by the Office of Translational Sciences Immediate Office in collaboration with subject matter experts from FDA.
  - Evaluation of materials for and participation in a CPIM by FDA subject matter experts is voluntary, and dependent on resources.
  - The CPIM is a general discussion that does not involve detailed evaluation of data.
  - The CPIM does not include any discussion of individual drug development programs.
  - CDER and other FDA participants' perspectives during the meeting will be consistent with CDER and FDA policy.
  - CPIM discussions and meeting summaries are nonbinding.
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## **RESPONSIBILITIES**

### **CPIM Project Manager**

- Notifies CPIM Scientific Lead of CPIM requests
  - Serves as the point of contact with requester and participating FDA Centers, Offices, and Divisions for administrative issues and the transfer of documents
  - Works with requester and FDA participants to establish the date for the CPIM
  - Manages CPIM database for knowledge management purposes
  - Keeps CPIM internet and intranet sites current
  - Responsible for the records management of all CPIM related activities
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- Distributes the meeting summary to the participants within 1 month

### **CPIM Scientific Lead**

- Evaluates whether a CPIM is an appropriate venue for the issue or topics raised by the requester
- Directs requester to appropriate FDA Center or Division if the requester's topics are not appropriate for a CPIM
- Communicates with the CPIM requester as needed to refine and clarify the nature of a CPIM request
- Solicits participation by FDA subject matter experts
- Chairs the CPIM pre-meeting and requester meeting
- Documents all discussions with the requester
- Writes the CPIM summary
- Writes a quarterly summary of topics covered at CPIM meetings and forwards it to the CPIM project manager for posting on internet

### **Consulted review Centers, Offices, and Divisions**

1. Choose appropriate staff to participate in specific CPIMs
2. Participate in pre-CPIM meeting and CPIM as resources permit
3. Edit and comment on draft meeting summary

### **Requester**

4. Submits CPIM Request Form
  5. Submits CPIM Preparation Package
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## **PROCEDURES**

### **Submission and Evaluation of the Request for a CPIM**

1. Groups interested in requesting a CPIM can find the CPIM Request Form available on the FDA internet site  
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm395888.htm> This form is directed automatically to [CPIMInquiries@fda.hhs.gov](mailto:CPIMInquiries@fda.hhs.gov)
2. The CPIM project manager will assign a project identifier to each request and forward the request form to the CPIM Scientific Lead.
3. The CPIM scientific lead will determine if the request is within the scope of the CPIM.
4. If the CPIM is determined to be within scope, the CPIM Scientific Lead will solicit participation of FDA subject matter experts.

### **Granting a CPIM**

1. The Project Manager will notify the requester if the CPIM request has been granted.

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2. If a request for a CPIM is not appropriate, the CPIM Scientific Lead will discuss this with the requester, and suggest potential other avenues to address the requester's needs.

### **Arranging a CPIM**

1. The project manager will establish the date for submission of the preparation package.
2. The project manager will make arrangements for the CPIM and the FDA internal pre-meeting.
3. The project manager will distribute the Preparation Packages to FDA participants.
4. In preparation for the CPIM, FDA staff will be asked to review materials in the preparation package. They will not be expected to provide written responses.

### **CPIM Activities**

1. An internal pre-CPIM meeting among the planned FDA participants is scheduled after the preparation package has been received and will be held within 30 days of the scheduled CPIM.
2. During the CPIM, all participants are invited to take part in the scientific discussion.
3. The CPIM Scientific Lead will draft a CPIM summary and distribute it within 5 working days after the meeting for comments and editing by all FDA participants.
4. The CPIM Project Manager will send a summary of the meeting should be sent to all participants within 1 month.

### **Record Keeping**

1. The CPIM Project Manager will maintain an archive of all CPIM records in accordance with the National Archives Records Administration (NARA) guidance.

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### **REFERENCES**

1. FDA draft guidance for industry, 2014, Critical Path Innovation Meetings.
2. FDA guidance for industry, 2014, Qualification Process for Drug Development Tools.
3. FDA, 2004, Challenges and Opportunities: Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products, Report.

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### **DEFINITIONS**

#### **Definitions –**

**Critical Path** -An initiative started in 2004 with publication of the FDA report *Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products*. The goals include driving innovation in the scientific processes through which medical products are developed and evaluated.

**Scientific Lead-** OTS Staff member appointed by OTS-IO to provide scientific leadership to the CPIM program.

**Project Manager** – OTS staff member assigned by OTS-IO to provide administrative and technical support for the CPIM program.

**CPIM Request-** Background information adequate to determine the appropriateness of the CPIM and for FDA to prepare for the CPIM.

**CPIM Preparation Package-** Submitted by requester, a statement of the objectives of the meeting, a proposed agenda, presentation slides, if any, and prospective attendees and their affiliations.

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**EFFECTIVE DATE**

This MAPP is effective upon date of publication.

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**CHANGE CONTROL TABLE**

| Effective Date | Revision Number | Revisions |
|----------------|-----------------|-----------|
|                |                 |           |
|                |                 |           |
|                |                 |           |

**ATTACHMENT 1**  
(Request Form Page 6)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Center for Drug Evaluation & Research  
Office of Translational Sciences  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

### Critical Path Innovation Meeting Request Form

|                      |                                                |                      |
|----------------------|------------------------------------------------|----------------------|
| Requester Name:      | Type of Organization:                          | Date: MM/DD/YYYY     |
| <input type="text"/> | Please select <input type="button" value="v"/> | <input type="text"/> |

Briefly describe the organization you represent:

Preferred format of the meeting: Please Select Format

Identify the purpose of the meeting, steps you have taken towards your goal, any specific questions for the FDA, and the desired outcome of the meeting:

We will contact you regarding your request.

[Submit Form Here](#)