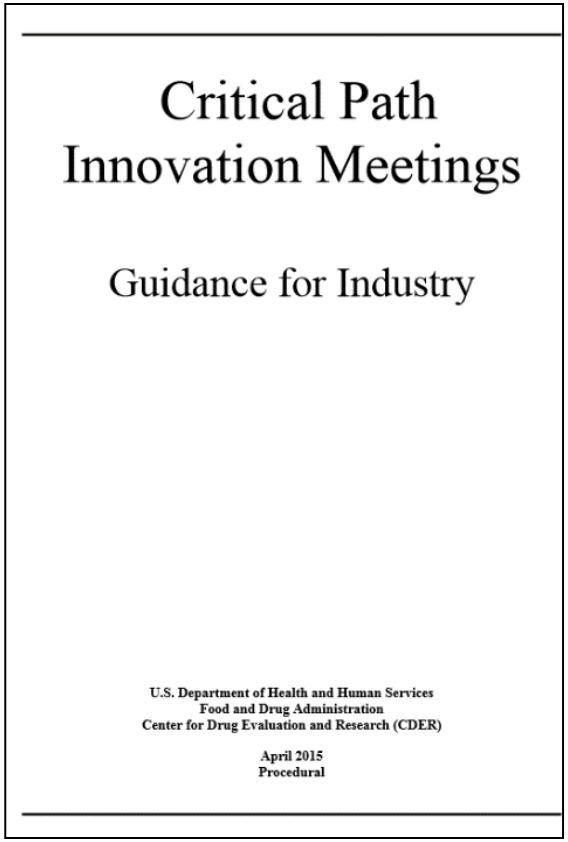
FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION & RESEARCH

Critical Path Innovation Meeting (CPIM)

Center for Drug Evaluation and Research (CDER)
Office of Translational Science (OTS)

Critical Path Innovation Meeting (CPIM)

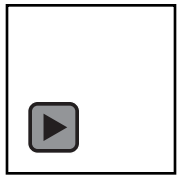
- Discussion of the science, medicine, and regulatory aspects of innovations in drug development; nonbinding
- Not a meeting about a specific approval pathway
- Scope includes early biomarkers and clinical outcome assessments, natural history studies, technologies (not manufacturing), and clinical trial designs and methods
- Outcomes include CDER perspective on role of innovation in drug dev ent; proposals for future collabora



http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm417627.pdf

Goal of the CPIM

CPIM provides an opportunity for stakeholders to communicate directly with FDA subject matter experts and have an open scientific discussion and exchange of ideas with a common goal of improving efficiency and success in drug development



CPIM Logistics

- Anyone with a role in drug development can request a CPIM.
- Requester fills out a one page form on the website.

- CPIM staff will evaluate the form to identify if CPIM is the right venue for the discussion.
- Acceptance of a CPIM is based on the relevance of the topic to drug development.
- CPIM staff work to identify subject matter experts and request their participation for the CPIM. In some cases, subject matter experts are invited from other Centers, including the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health.

CPIM Logistics

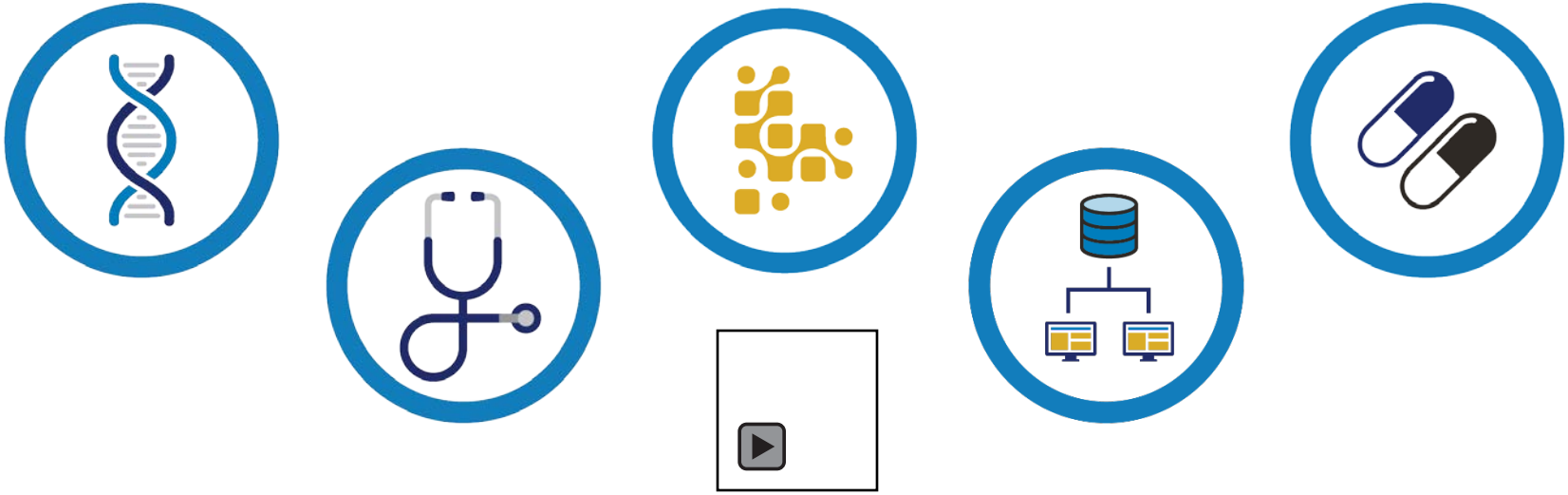
- Requester provides slides two weeks before the CPIM
- Pre-CPIM meeting one week before the CPIM
  - Orient internal participants to meeting structure
  - Identify areas to discuss/not discuss
  - Identify other participants to be invited

- 1.5 hours in length
- Presentation/scientific discussion led by the requester
- No discussion of policy, guidance, individual drug development programs
- Last 5-10 minutes for next steps

CPIM Outcomes

- Brief, high-level summary written by OTS and shared with the requester
- Topic area added to the website
- Outcomes have included: follow up with a specific CDER office/division or another Center; suggestion to have a public workshop or collaborate with other external groups; RCA/CRADA

CPIM Topics



- Clinical Trial Endpoints
- Biomarker Development
- Drug Development Tools
- Innovative Trial Designs
- Clinical Trial Networks
- Natural History Studies
- COA Development
- Rare Diseases
- Databases
- Registries

FDA

Drugs

Home > Drugs > Development & Approval Process (Drugs) > Drug Innovation

Drug Innovation

- Novel Drug Approvals for 2016
- Novel Drug Approvals for 2015
- Novel Drug Approvals for 2014
- Novel Drug Approvals for 2013
- Novel Drug Approvals for 2012
- Novel Drug Approvals for 2011

Resources for You

- Critical Path Innovation Meetings (CPIM)
- Critical Path Innovation Meeting (CPIM) FAQ's
- Critical Path Innovation Meeting (CPIM) Topics Held to Date

Critical Path Innovation Meetings (CPIM)

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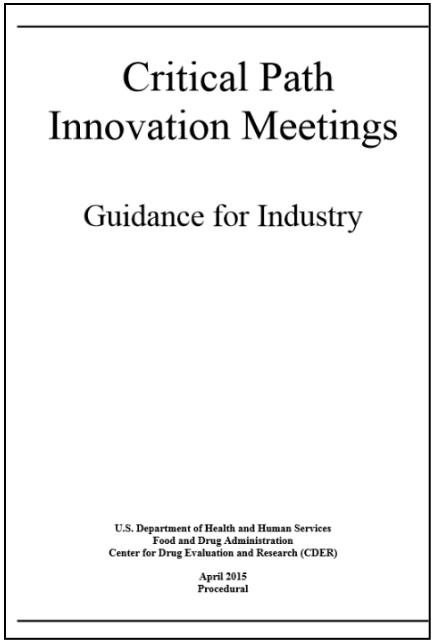
The Critical Path Innovation Meeting (CPIM) was developed by CDER to address issues in drug development identified in the 2004 FDA publication, *Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products Challenges and Opportunities Report*. The report identified several areas of product development in need of improvement, including "technical methods such as animal or computer-based predictive models, biomarkers for safety and effectiveness, and new clinical evaluation techniques," and cited a need "to create better tools for developing medical technolo ge base built not just on ideas from biomedical research, but on reliable insights into th s."

The CPIM is a means by which the Center for Dru earch (CDER) and investigators from industry, academia, patient advocacy groups, and nunicate to improve efficiency and success in drug development. The goals of the CP ethodology or technology proposed by the meeting requester and for CDER to provide ge his methodology or technology might enhance drug development. CDER will identify some of the larger gaps in existing knowledge that requesters might consider addressing in the course of their work. CDER expects to become more familiar with prospective innovations in drug development, broadening its regulatory perspective. The discussions and background information submitted through the CPIM are drug product-independent and nonbinding on both FDA and CPIM requesters. The meeting does not substitute for formal pre-IND, IND, NDA, or BLA meetings.

Potential topics for a CPIM include, but are not limited to, the following:

- Biomarkers in the early phase of development and not yet ready for the Biomarker Qualification Program (BQP)
- 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



Critical Path Innovation Meetings

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

April 2015
Procedural

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm417627.pdf

Questions

If you have questions, please send any inquiries to:

CPIMInquiries@fda.hhs.gov

Thank you for your interest in the CPIM Program!