
INFORMATION TECHNOLOGY

**INFORMATION MANAGEMENT STEERING COMMITTEE (IMSC)
PLANNING SUBCOMMITTEE**

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PURPOSE

This MAPP describes the organization and responsibilities of the Information Management Steering Committee (IMSC) Planning Subcommittee and the procedures for bringing proposals for new Information Technology (IT) Projects to the IMSC Planning Subcommittee in the Center for Drug Evaluation and Research (CDER).

BACKGROUND

The IMSC Planning Subcommittee is a subordinate group to the CDER Information Management Steering Committee (IMSC), whose membership includes members of the CDER Senior Management Team (SMT). The Planning Subcommittee makes recommendations and reports progress to the CDER IMSC regarding proposals for new IT Projects. This subcommittee has been established to:

- Evaluate strategic information management needs of CDER staff from an enterprise perspective.
 - Make recommendations for approval, prioritization, and funding of IT projects based
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on the information management needs of the Center.

- Monitor progress and status of prioritized CDER IT Projects.
- Evaluate and make recommendations regarding IT policy.
- Develop and maintain an Information Management (IM)/Information Technology (IT) Action Plan for CDER.

Additional information regarding the subcommittee can be found on the CDERnet at http://cdernet/ocd/imsc_planning_subcom.htm.

This MAPP supersedes two other MAPPs that are being withdrawn: (1) MAPP 7600.1 Information Management Steering Committee, which will be rewritten, and (2) MAPP 7600.5 Requesting IT Services from the Office of Information Technology.

DEFINITIONS

- **Information Management (IM):** Information Management at CDER means:
 1. Supporting Center staff and Business Units to identify business needs and business processes that would benefit from the application of Information Technology.
 2. Supporting Center staff and Business Units by developing *business cases* for applying information technology to business processes, analyzing alternative solutions, and re-engineering business processes as necessary.
 3. Managing drug applications in the Center Document Rooms.
 4. Entering data about the drug applications into the CDER corporate database.
 5. Developing and maintaining business and data layers of the Enterprise Architecture (EA) for the Center.
 6. Managing the processes for entering data into and generating reports from CDER applications (e.g., Drug Registration and Listing System (DRLS), Postmarketing Commitments (PMC)).

In CDER, the Office of Information Management (OIM) will perform these functions.

- **Information Technology (IT):** At CDER, Information Technology means:
 1. Planning, managing, and conducting Requirements Analyses for developing new or modifying existing CDER corporate IT systems.
 2. Planning and managing the process to design, develop, and implement IT systems based on the requirements identified.
 3. Ensuring the continued reliability and availability of existing Center IT Systems.
 4. Obtaining and managing any required contract resources to design, develop, and implement or maintain IT systems.

The CDER Office of Information Technology (OIT) within the Agency Office of the Chief Information Officer (OCIO) will perform these functions.

- **Office of Information Technology Shared Services (OITSS):** For CDER, the OCIO Office of Information Technology Shared Services (OITSS) will:
 1. Maintain network operations and perform upgrades.
 2. Maintain desktop computer operations and perform upgrades.
 3. Perform system production server maintenance.
 4. Provide customer service support.
- **CDER Business Unit:** Any segment of the Center staff. For example, a business unit could be an Office or Division in the Center organizational structure, or a business unit could be the regulatory project managers.
- **IT Project:** An IT Project is a discrete software development effort that has a definite beginning and end. *IT Project* at CDER includes any project that involves the use of information technology to automate a business process or to develop new systems or improve existing systems. IT Projects include projects to develop new software or enhance existing software, including those pursued under a contract or via a Cooperative Research and Development Agreement (CRADA).

REFERENCES

- CDER Information Technology/Information Management Process Guide (<http://oitweb/itcommittees/>)
 - FDA Software Development Life Cycle (<http://intranet.fda.gov/ocio/SPS/PMO/Repository/default.htm>)
 - FDA Enterprise Architecture Policy (http://oitweb.cder.fda.gov/programs/ea/small_scale.shtm)
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ORGANIZATION

Co-Chairs: The IMSC Planning Subcommittee is co-chaired by a member of the strategic planning staff within the CDER Office of Executive Programs and by the CDER Associate Director for Medical Informatics.

Membership: Membership will include representatives of the Center Offices as nominated by the CDER SMT.

POLICIES

- A proposal for a new IT Project must be submitted to, and reviewed and approved by, the IMSC Planning Subcommittee before proceeding as a project (see Attachment A for a proposal template).
 - This MAPP applies to all IT Projects that meet any of the criteria delineated in the *Procedures* section of this document.
 - No Center financial or personnel resources will be devoted to IT proposals that have been denied by the IMSC Planning Subcommittee and/or the IMSC.
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RESPONSIBILITIES

The Co-Chairs of the IMSC Planning Subcommittee will:

- Arrange, organize, and conduct IMSC Planning Subcommittee meetings on a biweekly basis.
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- Manage and maintain the subcommittee and its activities.
- Maintain IMSC Planning Subcommittee files (Project Priority Lists, IT proposals, action items and decisions, status reports of IT Projects, CDER IM/IT Strategic Plan).
- Distribute meeting-related background documents and minutes.
- Ensure that IMSC Planning Subcommittee recommendations and proposed policies regarding information management are communicated to the IMSC members.
- Communicate IMSC Planning Subcommittee and IMSC recommendations and decisions to the IT Project requestors.

Members of the IMSC Planning Subcommittee will:

- Represent their organizational units' views on issues being considered by the IMSC Planning Subcommittee.
- Communicate with their organizational units about the deliberations of the IMSC Planning Subcommittee and the IMSC.
- Keep their respective SMT member apprised of current issues and Subcommittee progress and discussions.
- Regularly attend meetings of the Subcommittee. If a member cannot attend a meeting, an alternate may be designated to attend. The alternate must be able to represent the organization and speak on behalf of the member. There will be no quorum requirements for conducting meetings. However, members unable to attend meetings and unable to send an alternate will review minutes of meetings missed to keep up with the Subcommittee's progress and recommendations.
- Develop, facilitate, and monitor progress toward the CDER IM/IT strategic plan.
- Deliberate on and recommend action on IT policies.
- Communicate and promote IMSC decisions to CDER staff and to other interested parties as appropriate.

IT Project Managers for approved IT Projects will:

- Submit a semiannual report on the status of each project to the IMSC Planning Subcommittee chair (see Attachment B for a template).
- Communicate regularly with the sponsoring business unit or units and to the Project's Business Sponsor on project status, requirements issues, and technical direction.
- Notify the IMSC Planning Subcommittee Co-Chairs of any new critical issues as they arise.
- Respond to additional information requests from the IMSC Planning Subcommittee or IMSC as needed.

Business units, with the assistance of CDER/OIM staff, will:

- Identify an information management problem or business need and prepare an IT proposal (see Attachment A) to be presented to the IMSC Planning Subcommittee.
 - Participate in an analysis of alternative solutions and prepare a justification or *business case* for implementing the optimal solution.
 - Support IT Projects and participate in those projects to ensure the product being developed meets the business needs identified.
 - *Accredit* the system or product to officially accept that the system or product performs the functions it is intended to perform within an acceptable margin of risk.
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PROCEDURES

IT Proposals and Projects

- **IT projects evaluated by the IMSC Planning Subcommittee** include those that meet one or more of the following criteria:
 1. Directly supports one or more of the Agency or Center strategic initiatives (e.g., directly supports the Critical Path Initiative).
 2. Is considered high profile (i.e., is of particular interest to the Agency Management Council or CDER Senior Management Team).

3. Requires significant funding for contractor support. A general guideline suggested is any IT software development contract for greater than \$25,000.
 4. Has dependencies on existing or future production systems (e.g., a proposal for developing an application that would pull data from the CDER Oracle Management Information System (COMIS)).
 5. Requires resources (e.g., staff time or contract support) from the IT organization.
 6. Will be used by a significant segment of the CDER staff. A general guideline suggested is more than one CDER Division.
- **IT Projects outside the scope of the IMSC Planning Subcommittee** generally include those that use only local (CDER Division/Office) resources (staff/funding) to develop, enhance, and maintain an IT application system. Examples include:
 1. Software intended for individual use.
 2. Purchase and use of client-based, commercially available off-the-shelf software (COTS) packages.
 3. Content management and management of Web pages to disseminate information.
 - **Projects designated as official CDER IT Projects**

To proceed as an official CDER IT Project, an IT Project that meets any of the six criteria listed above (see the subsection titled *IT Projects evaluated by the IMSC Planning Subcommittee on p. 6*) must reach two major milestones of IMSC Planning Subcommittee review:

1. Milestone 1: A recommendation by the IMSC Planning Subcommittee to the IMSC to accept an IT Project proposal and proceed to the next step of developing a project Boundary Document.
2. Milestone 2: A recommendation by the IMSC Planning Subcommittee to the IMSC to accept the Boundary Document and to fund the IT Project.

The CDER IMSC has the prerogative to accept, modify, or deny recommendations of the Planning Subcommittee at either milestone.

Any questions regarding what is considered an IT Project for consideration by the IMSC Subcommittee should be submitted by e-mail to the Director of CDER OIT. However, all IT CDER Projects and applications, regardless of size and scope, should be consistent with the standards of the CDER Enterprise Architecture and be accounted for in the EA. Therefore, sponsors of IT Projects that do not require IMSC Planning Subcommittee review should refer to the OIT Web site at http://oitweb.cder.fda.gov/programs/ea/small_scale.shtm for further information.

Any questions regarding how to comply with the CDER Enterprise Architecture should be submitted by e-mail to the Director of CDER OIT.

- **Procedures for achieving Milestone 1 of Subcommittee review:**
 1. A CDER business unit identifies an Information Management problem and/or business need and prepares an IT Proposal (see Attachment A for a proposal template). OIM Staff support the business unit in the completion of the IT Proposal. The IT Proposal is submitted to the IMSC Planning Subcommittee for review.
 2. The IMSC Planning Subcommittee Co-Chairs will schedule discussion of a new proposal on the next available meeting agenda.
 3. The IMSC Planning Subcommittee will evaluate any proposals and assign a recommendation of *accept*, *defer*, or *reject* based on the following criteria:

Decision	Criteria
Accept Request	One or more of the following: <ul style="list-style-type: none"> • Extension of critical, existing production system • Mandate (e.g., Congressional, Departmental, or Agency) • Supports Department, Agency, and Center Goals • High benefit • Low risk (including technical feasibility, impact on CDER if fails) • Low cost
Defer Request <i>A deferred request can be pursued in the future as resources permit. Open requests are automatically reconsidered in the next fiscal year by the IMSC.</i>	One or more of the following: <ul style="list-style-type: none"> • Low priority (low urgency) • Marginal cost/benefit ratio • Resource constraints
Reject Request <i>A rejected proposal is not to be pursued unless it is resubmitted for consideration in the future.</i>	One or more of the following: <ul style="list-style-type: none"> • Contrary to policy, strategic direction, mission, or established standards • Duplicate • Poor combination of cost, benefit, and risk

4. If a proposal is accepted, the IMSC Planning Subcommittee will determine the project’s relative importance to all other IT Projects underway in the Center.
5. Once a proposal has been accepted and prioritized, the IMSC Planning Subcommittee Co-Chairs will place the item on the agenda for the next IMSC meeting to discuss the Subcommittee’s recommendation.
6. If the IMSC agrees with the Subcommittee’s recommendation (hence, Milestone 1 is reached), the IMSC will identify key IT Project stakeholders, including the Business Project Sponsor, the Business Project Manager/Product Owner, and Change Control Board (CCB) members. These stakeholders will carry out the following activities:
 - Business Project Sponsor – The Business Project Sponsor is the FDA Executive responsible for ensuring that appropriate organizational support and funding are assigned and maintained for the IT investment. The Sponsor continues leadership and oversight throughout the system life cycle.
 - Business Project Manager/Product Owner – The Business Project Manager/Product Owner is assigned by the Business Project Sponsor and

is the business representative responsible for the day-to-day functions of the product and/or area of business. The Business Project Manager/Product Owner represents the Sponsor and will engage appropriate business Subject Matter Experts (SMEs), deliver business-generated documents, ensure that user requirements are met throughout the system life cycle, and be accountable to the Sponsor.

- CCB Members – Members of the Change Control Board will review and prioritize proposed changes to the product. CCB members will make day-to-day decisions regarding the product and affected business functions.

- **Procedures for achieving Milestone 2 of Subcommittee review:**

1. The Business Project Sponsor, with the support of the Business Project Manager/Product Owner, OIT, and OIM, will analyze alternatives and create a Boundary Document that includes a definition of the project scope and an explanation of the results of an alternatives analysis.
2. Concurrent to the time frame in which the Boundary Document is developed, the CDER Enterprise Architect will conduct an impact analysis of the described system on the current environment. The CDER Enterprise Architect will review the results of the analysis with the developers of the Boundary Document.
3. The Sponsor (or designee) will present the Boundary Document to the IMSC Planning Subcommittee. The CDER Enterprise Architect will present the results of the EA Impact Analysis. The IMSC Planning Subcommittee Members will then determine whether to recommend pursuing the project.
4. The IMSC Planning Subcommittee will recommend whether to accept the Boundary Document and initiate the project and will notify all appropriate individuals of the Subcommittee's recommendation.
5. The IMSC Planning Subcommittee Co-Chairs will brief the IMSC on the recommendation of the Subcommittee.
6. If the IMSC approves the recommendation of the Subcommittee (i.e., Milestone 2 is reached), the IMSC Co-Chairs will notify the appropriate individuals of the IMSC decision. Further, the Director of CDER OIT will assign an IT Project Manager, a Technical Lead, and a Product Manager to the IT Project. These individuals will carry out the following activities:
 - OIT Project Manager – Plan, lead, and manage all work necessary to conduct requirements analysis; design how the work will be

accomplished; and develop, test, and implement the solution.

- OIT Technical Lead – Provide support to the OIT Project Manager and technical team during the design, development, integration, testing, and implementation. Once the product is implemented, the technical responsibilities are turned over to the OIT Product Manager.
 - OIT Product Manager – Plan, lead, and manage all work for the continued operation, reliability, availability, and security of the system after implementation.
- **Progress reporting**

Once an IT Project has successfully achieved both milestones of review, the following progress reporting procedures will be required:

1. All OIT Project Managers and Business Project Managers/Product Owners will provide periodic updates to the IMSC Planning Subcommittee on project status using the reporting format provided in Attachment B.
 2. The IMSC Planning Subcommittee Co-Chairs will ensure that the IMSC receives periodic updates on the IT Project status.
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DISPUTE RESOLUTION

CDER staff wishing to contest a recommendation made by the IMSC Planning Subcommittee can request review of the CDER IMSC decision by contacting one of the IMSC Planning Subcommittee Co-Chairs, who will coordinate discussion of the issue with the IMSC.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Attachment A

*Complete this proposal template if your proposed IT Project meets any of the criteria listed in this MAPP under the subsection titled **IT Projects evaluated by the IMSC Planning Subcommittee** (see p. 6).*

Request for Review of IT Proposal

Title of Proposal:
Sponsoring Office:
Point of Contact:
Data Submitted:

Justification for Project	
1.	What is the business need (i.e., what Center strategic goals does this meet)? Describe the problem that you are trying to solve.
2.	What Center business process does this project support?
3.	If this request is a response to a mandate or to a known Center commitment, describe the mandate or commitment.
4.	How will this project support the Center's mission?
5.	What public health benefit, if any, could be derived from this project?
6.	How many potential end users are there (i.e., what business segments of the Center, Agency, Department, and/or other Government Agencies would benefit from this project)?
7.	How will this project improve productivity or make the business process more efficient?
8.	Based on your knowledge, is this request unique, or are there other known similar needs in the Center?
9.	What are the projected savings, if any, to the Center if this system is implemented?
10.	What is the impact to the Center of not pursuing this effort?

11. Is this request time-sensitive? If so, what is the time sensitivity?
Potential Solution
12. If you have one, state the concept for an IT solution to be used to meet the business need defined in Question 1 above.
13. Name any known dependencies on other IT systems.
Resources
14. Who is the Business Project Sponsor? (The Sponsor is a senior manager who represents the business function that would benefit from this project.)
15. Who will be the product owner? (The product owner is a business person responsible for day-to-day operations, intimate knowledge, and decisions about the product developed as a result of this project.)
16. Has your office made any provisions for backup ownership of the product (i.e., to reduce the potential risk of intimate knowledge of the product residing with a single person)? If so, what provisions have been made?
17. What resources (e.g., staff, equipment) from OIT are anticipated for this project?
18. What resources from OIM (staff) are anticipated for this project?
19. Describe any resources available in your organization to accomplish this project.
20. What are the costs associated with known hardware, software, license, or other needs associated with this proposal?
21. What is the anticipated source of the funding (i.e., PDUFA vs. non-PDUFA)?

IMSC Decision:

Date

Attachment B

IT Project Progress Report

Project Title: _____

Project Contact: _____ **Phone:** _____

Project Description: Describe the scope of the project and expected accomplishments, outcomes, or products. Identify the major stakeholders and customers. Identify internal and external project dependencies when applicable.

IT Solution: Describe the methodology and technology being applied to satisfy the business need. The extent of the description will vary based on the size and complexity of the project. Attach available descriptive diagrams that show how the solution will work (e.g., Conceptual Diagram, Architecture Diagram, Process Flow Charts).

SCHEDULE: List the major life cycle milestones associated with this project.

Major Milestone	Planned Start Date	Actual Start Date	Planned End Date	Actual End Date

Provide project cost data and dollar estimates.

	Budgeted (FY XX)	Actual (FY XX)	Budgeted (FY XX+1)	Actual (FY XX+1)	Total Budgeted	Total Actual
Dev/ Mod./ Enhancement						
Maintenance/Steady State						
Total						

If a project is over budget, behind schedule, or below performance expectations, please describe the reasons why and the corrective actions being taken to get the project back on track.