OFFICE OF TRANSLATIONAL SCIENCES

CDER Science Projects Database

CONTENTS

PURPOSE

- This MAPP establishes a process for capturing and archiving information about CDER science and research projects in the CDER Science Projects Database. The MAPP specifies responsibilities for entering, reviewing and approving content, and for general oversight of the CDER Science Projects Database.

BACKGROUND

The Center for Drug Evaluation and Research (CDER) requires a systematic tool to capture, archive, and communicate effectively about its science efforts, including research and other science projects undertaken to support its regulatory and public health mission. The CDER Science Projects Database provides an important tool to support prioritization, management, and review of the quality and impact of CDER's science investments.

The CDER Science Projects Database will serve as a science and research management tool by:

1. Providing a descriptive inventory of all current CDER science and research projects and programs.
2. Providing an archival record of past science and research activities.
3. Providing information critical to the effective management of research programs, including progress reports and information on outcomes, effort, collaborations, and special funding.

The CDER Science Projects Database will also provide an important communications tool to:

1. Improve dissemination of information about science and research efforts to the FDA scientific community via *Inside FDA*, to the public via the internet, to other governmental entities such as NIH, CDC and Congress, and to industry, consumer and patient organizations, academic partners and other stakeholders.
2. Empower CDER scientists to clearly communicate the nature, importance and regulatory impact of their science and research projects/programs to a broad audience.

REFERENCES

- CDER Science Projects Database on *InsideFDA*
  http://inside.fda.gov:9003/ProgramsInitiatives/Drugs/ScienceResearch/ucm035466.htm
- CDER Science & Research pages on *InsideFDA*
  http://inside.fda.gov:9003/ProgramsInitiatives/Drugs/ScienceResearch/default.htm
- Regulatory Science And Review Enhancement (RSR) Program
  http://inside.fda.gov:9003/ProgramsInitiatives/Drugs/ScienceResearch/ucm193804.htm
- Critical Path Initiative funding
  http://inside.fda.gov:9003/ProgramsInitiatives/Drugs/ScienceResearch/ucm193808.htm
- FDA Amendments Act of 2007, Sec. 910
- CDER MAPP 4112.8 posted 5/22/06. Research Coordinating Committee
  http://www.fda.gov/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/default.htm

---

DEFINITIONS

- **Project Lead** – The person who has primary responsibility for the conduct of a project/program described in the Database. The Project Lead is the primary point of contact for project/program information and has responsibility for maintaining the Science Projects Database record for their project/program(s). Project Leads are appointed by the Office or Division Director, or their designees.
- **Database Record** - a collection of information describing a science or research project or program. Each database record includes the project/program title, lead, summary, collaborators, mission relevance, accomplishments, publications and special funding information.
- **Database Record Approver** – The individual responsible for reviewing and approving the contents of each project/program database record assigned to them. Database Record Approvers are appointed by their Office Directors.
- **Project** - A research activity of limited scope and goals that represents an organized effort to answer a specific research question. A project should have the approval of the Office Director or his or her designee (e.g., Division Director or Laboratory Chief) and reflect some minimum level of effort leading to an archived output, such as a research report or publication. The expectation is that projects will have a defined end point.
- **Program** - A program is an extended research effort without a defined end point that addresses a broad scientific area and consists of a number of inter-related projects.
- **Science Projects Database Working Group** ("Working Group") - a CDER working group of the Research Coordinating Committee that has primary responsibility for determining database content and design, as well as data entry and use practices.
- **CDER Research Coordinating Committee** (RCC) –The CDER committee that coordinates research-related practices and activities for CDER.
- **Research in Human Subjects Research Program** (RIHSC)
  http://inside.fda.gov:9003/ProgramsInitiatives/Drugs/ScienceResearch/ucm035467.htm

---

POLICY

All approved research and science projects or programs conducted and/or funded by CDER must be captured in the CDER Science Projects Database. This includes all intramural or contracted laboratory and non-laboratory research, all human subjects research, all projects funded by intramural programs, including the Regulatory Science and Review Enhancement Program (RSR), Critical Path Initiative (CPI), Office of Women's Health (OWH), Chief Scientist's Challenge Grants, and all science or research projects funded by non-FDA sources, including NIH Bench to Bedside awards, Cooperative Research and Development Awards (CRADAs), Interagency Agreements (IAs), and Contracts.

- The CDER Science Projects Database will be a definitive reference for CDER's science and research efforts. Data entered, reviewed and approved will be used to support science and research planning, budgeting, reporting, and review.
- All records will be updated, reviewed, and approved annually during the first quarter of each fiscal year (Oct 1 through December 31).

RESPONSIBILITIES

Project Leads

- Populate and annually update project/program records for all approved projects/programs they lead.
- Ensure that project/program personnel and effort information are accurate by confirming with each CDER participant listed.
- Ensure that project/programs completed during the course of a fiscal year are closed out in the database, that an end date is provided, and that all progress, final reports, and publications resulting from the project/program are captured in the database.
- Complete all database entry updates by the end of each calendar year.

Database Record Approvers

- Monitor status of project updating and ensure that Project Leads complete their project/program records and updates during the first quarter of each fiscal year.
- Review in full for accuracy, clarity, and completeness the database records for all projects/programs for which they have review responsibility by the end of the first quarter of each fiscal year.
- Request additions/revisions of database entries by Project Leads as appropriate.
- Ensure that when projects/programs end, the end date is captured in the final database record, along with updated publications and final reports.

Office Directors or Designees

- Assign Database Record Approvers for each project.
- Assign Project Leads for each project.
- Approve a list of ongoing, new, and completed projects for inclusion in annual updates.

CDER Science Projects Database Working Group

- Defines the requirements of the Science Projects Database in order to meet the needs of all stakeholders, including CDER and FDA management.
- Annually evaluates the database and decides on changes needed in data fields, functionalities, or governance of the database.

- Determines which data fields in the database should be viewable on *InsideFDA*. For specific projects, Offices may request that sections normally displayed on the *InsideFDA* site not be displayed.
- Informs RCC and CDER management of important updates in function or policy regarding the database.
- Reviews and approves SOPs for database maintenance and quality control developed by OTS.

Office of Translational Sciences/Immediate Office (OTS/IO)

- Maintains the database infrastructure.
- Provides project management and meeting facilitation for the Working Group meetings.
- Implements annual changes to database structure determined by the Working Group.
- Provides training, instruction, and support for completing, reviewing, and approving database records.
- Acts as primary point of contact for questions regarding database use and data entry.
- Develops detailed instructions (e.g., quality control review, timeline development, procedures for new project/program entry and archiving) for maintenance and quality control of the database.
- Provides to CDER managers reports derived from the database (e.g., a summary of efforts within their divisions, by project/program, and by person), upon request.
- Sets up new records and access for new projects/programs for inclusion in the database, as requested by Offices.
- Communicates with Offices to ensure identification of the appropriate Database Record Approvers for each project/program record.
- Ensures that instructions for logging into the database and completing a database entry are updated and posted on the *InsideFDA* CDER Science & Research pages.
- Provides an annual upload of requested data to the FDA Research Database maintained by the Office of the Commissioner.

CDER Research Coordinating Committee (RCC)

- Provides input to the Working Group on enhancements or issues related to the management and use of the database.

PROCEDURES

The CDER Science Projects Database entry pages are designed to minimize the time and effort required to complete or update records. Drop-down menus and radio buttons will be used, where possible, to simplify data entry. For projects funded by special programs such as the Regulatory Science and Review Enhancement (RSR) Program or the Critical Path Initiative, much of the information in new records will be pre-populated from application forms. Once a project record has been completed, annual updates involve describing the past year's progress and adding relevant publications.

Detailed instructions on updating, finalizing, and approving database records and points of contact are available on the CDER *InsideFDA* CDER Science and Research Resources page at:.
http://inside.fda.gov:9003/ProgramsInitiatives/Drugs/ScienceResearch/ucm035466.html

An office may choose to group inter-related projects together into programs, having one database entry for the entire program, or may elect to enter specific projects individually. It is expected that program

entries will include descriptions of all activities, progress, participating personnel, outcomes, and publications associated with all of its component projects. It is important that information in the database be accurate, complete, well written, and updated annually.

Identifying New and Ongoing Project/Programs for Annual Updating:

To ensure that the list of active projects for each fiscal year accurately reflects ongoing and newly initiated projects, OTS will follow the steps outlined below:

- In preparation for record updating, OTS will create a list for each Office annually that includes active database records, and new activities, such as newly funded Critical Path Initiative (CPI) and RSR projects, and projects newly approved by the Research in Human Subjects Committee (RIHSC). OTS will send the list to the appropriate office director or designee. Each Office will then determine the final list of ongoing and new projects, and will assign Project Leads and a Database Record Approver for each project.
- OTS will set up new records, and consolidate ongoing projects, as requested.

Completing, Updating, and Closing of Science Projects Database Records:

Project Leads will be expected to update their ongoing project/program records and complete new project records prior to the end of the first quarter of each fiscal year. Detailed instructions can be found on the CDER Science & Research Resources page at:
http://inside.fda.gov:9003/ProgramsInitiatives/Drugs/ScienceResearch/ucm035466.htm

- OTS will send periodic reminders to Project Leads by email while the database is available for updating.
- Project Leads for ongoing projects/programs will log into the database using their existing usernames and passwords. All project/programs for which they are responsible will be displayed for editing.
- New Project Leads will enter their usernames (the username is the first part of their FDA email address, e.g., 'John.Doe'), and will create a password.
- Project Leads should completely and accurately update the information in their database record(s). Updates will reflect activity and progress during the previous fiscal year.
- On completion of each section, the Project Lead should finalize each section, as described in the detailed instructions as referenced in the link above.
- If additions, revisions, or corrections are requested from the Database Record Approver, the Project Lead will make needed changes and finalize the record.
- If a project/program is completed during the fiscal year, the Project Lead should change the status from "active" to "complete" and enter a completion date in section A.

Reviewing and Approving Updated Database Records:

Database Record Approvers should review and approve records by the end of the first quarter of each fiscal year.
http://inside.fda.gov:9003/ProgramsInitiatives/Drugs/ScienceResearch/ucm035466.htm

- Database Record Approvers will monitor the progress of project/program entry updates by viewing their Administrative List, located at: http://research.cber.fda.gov:591/CDER_Project_Updating/entry.htm.

- Once all sections of a project record have been updated and finalized by the Project Lead, Database Record Approvers will review the entire contents of each finalized record, including participating personnel and effort, to ensure accuracy.
- Should there be deficiencies or inconsistencies, the Database Record Approver will request additions, revisions, or corrections from the Project Lead(s) as needed.
- Once the database entry is accurate and updated, the Database Record Approver will approve the entry on-line. Detailed instructions for reviewing and approving entries are available at http://inside.fda.gov:9003/ProgramsInitiatives/Drugs/ScienceResearch/ucm035466.htm
- When all projects updates are complete and approved, OTS will transfer updated project information to the live database site, making it accessible through *InsideFDA*.

EFFECTIVE DATE

This MAPP is effective upon date of publication.