MIAP - Review a Study Application / Amendment

When a new study application or amendment requiring MIAP review is submitted, it automatically displays in the MIAP Reviewer’s home workspace. If a study doesn’t meet the criteria to trigger automatic MIAP review, applicable Ancillary Committees, IRBs and MIAP can manually assign a submission for MIAP review using the Update MIAP Review Requirements activity in the applicable submission workspace.

- Initial submissions (no MIAP Staff Owner assigned) display on the Unassigned tab.
- Submissions with a MIAP Staff Owner assigned display on the MIAP Staff Owner’s My Inbox tab.
- All submissions requiring MIAP review, regardless of Owner, display on the Office tab.

This document demonstrates review of a new study application that has automatically triggered MIAP review and has not yet had a MIAP Staff Owner assigned.

Review an Application or Amendment

MIAP Home Workspace > Unassigned tab

1. Click MIAP under My Roles, or verify that it is selected.
2. Click the Unassigned tab.

**Note:** If desired, click Execute Activity and skip to step 4 to review without opening the submission. Otherwise, continue with step 3.
3. Click the Name of the submission requiring review from either the Applications or Amendments list.

**Note:** The following demonstrates study application review; steps to review an amendment are identical.

Submission Workspace

4. Click Assign MIAP Owner from the Activities list (shown) or using Execute Activity (not shown).
5. Begin typing the name of the MIAP staff member you wish to assign as owner, and then select their name from the predictive list that displays.

**Note:** Alternatively, click Select to search for the person or to view a complete list of people.
6. Click OK.

**Note:** The submission moves from the Unassigned tab to the MIAP Staff Owner’s My Inbox tab.
7. To enter MIAP review details, MIAP contingencies, and/or complete the MIAP review, click Complete MIAP Review from the Activities list (shown) or using Execute Activity (not shown).
8. Click **Update** to edit or resolve any issues Created By or Assigned To MIAP Staff.
9. Click **Add** to identify a new issue, if desired.
10. Enter **MIAP internal review details** in the field provided.
11. If desired, click **Add** to upload any review-related documents.
12. If further MIAP review of the study is needed, click **No** for the question, **Further MIAP review not required?** If MIAP review is complete for the study, click **Yes**.
13. Click **OK**.

If further MIAP review is needed, the submission can be found either on the MIAP Staff Owner’s **My Inbox** tab or on the **Office** tab.

If MIAP review is complete, the submission displays on the **Previously Reviewed Studies** tab, and the message in the submission workspace changes from **MIAP Review In Progress** to **MIAP Review Complete**.

**Additional Activities:** The following activities are also available for MIAP Staff to use as needed. These activities can be found in the applicable submission workspace:

**Update MIAP Review Requirements** – Execute this activity in order to require MIAP review on a submission that otherwise would not trigger automatic MIAP review. The submission will display in the **Unassigned** tab of the MIAP workspace.

**Manage FDA Documents** – Available to both study teams and MIAP, execute this activity to upload specific FDA documents listed in the activity window. Documents uploaded via this activity are visible on the **Documents/Related Records** tab.

**For Ancillary and MIAP** – Execute this activity to correspond directly with Ancillary Committees. Correspondence in this used via this activity is visible on the **MIAP** tab.

**For MIAP and Core Committees Only** – Execute this activity to correspond directly with IRBs. Correspondence in this used via this activity is visible on the **MIAP** tab.

**For MIAP Only** – Execute this activity to correspond directly with other MIAP staff. Correspondence in this used via this activity is visible on the **MIAP** tab.

**Post Correspondence** – Execute this activity to post a message in the **Activities and Correspondence** section at the bottom of the submission workspace, which is visible to anyone with access to view the submission.