Processing a Governance Milestone

The following Governance milestones are processed via Research GEMS:

❖ **First Patient In:** First Patient In data is collected for SA metrics 5. The Research Office does not need to review or process this milestone.

❖ **Certificate of Currency:** For Commercial and Collaborative Group sponsored Clinical trials. *Can be processed via the Project Milestones section or Project Decisions section but it is **recommended to process via Project Decisions section.***

❖ **Progress Report – External HREC:** HREC approved progress reports from a HREC external to GEMS must be submitted to the RGO. *Milestone is automatically 'Achieved' upon submission.*

Processing a milestone from the SSA Project Milestone section

*Note: This User Guide assumes you have already set up your homepage tiles. See **User Guide– Research Offices – [Setting up Homepage tiles](#)***

Select the milestone to be processed from the Milestone homepage tile. You are taken directly to the Milestones 'Information' section.

Note: The following instructions can be used for the Certificate of Currency and First Patient In governance milestones.

Step 1.
Select 'Edit' and 'Process milestone'. Complete the progress report in the 'Process milestone wizard'.

Step 2. Process (First Patient In or Certificate of Currency) Milestone

Date received: Date the milestone was initially submitted. This should not be changed.

Milestone status: Select appropriate status from the dropdown menu:
Achieved: Milestone report noted and accepted by the RGO.
Revision: Further information is required. Complete the additional information required.
These statuses require a date to be selected for when the milestone should be returned. Click the 'Update milestone due date' toggle to update the due date.
Not Achieved: When a milestone is not submitted even after multiple requests. Complete the additional information required.

Effective Date: Date decision made**.** Click on the red arrow on the right-hand side to proceed through sections 2-4.

Step 3. Attach minutes Functionality currently not used.

Step 4. Rate milestone Functionality currently not used.

Step 5. Send milestone email
The 'Send Email' toggle is automatically listed as 'Yes', if you do not wish to send an email, click the 'Send Email' toggle to 'No'.

Edit the email as required. You can reload the email template by clicking the 'Reload email template' button.

This will revert the email back to the original template, removing any information manually added.

Click the green tick to send the email.

Change the Status of the Project.

When an external progress report has a status of Completed, Closed (post analysis), Terminated or Abandoned it is noted that the Research Office should change the status of the Site Project.

Step 1.

In the Site 'Project', select 'Management' and 'Status'. Select Edit and '+ Add status'. Once completed, select 'Ok' and 'Save'.

Automatically Shared with Authorised Sites in GEMS

When the milestone is 'Achieved', PI's listed in GEMS will receive a copy of the decision notification and the Progress Report – External HREC will be automatically shared with all sites in GEMS.

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Navigate to 'Related documents' and using the aggregate view, identify the 'Milestone Report' and 'System Generated Email'

Processing a milestone from the SSA Project Decisions section

Select the milestone to be processed from the Decision homepage tile. You are taken directly to the 'Decisions' section of the Project.

Note: An RGO review of Certificate of Currency and RGO review of a Progress Report are automatically created upon submission of these type of milestones.

Step 1.

 Locate the 'RGO review of Certificate of Currency' or 'RGO review of a Progress Report' decision as appropriate. Select 'Edit' from the right-hand side of the screen.

Step 2.

Select the 'Edit' icon on the row of the decision you are processing.

Note: Research Governance Officer/s will be automatically listed as the 'User' against the decision, this is dependent on who your Research Office has listed as a 'Research Governance Officer' in the system.

Select the 3 horizontal dots at the end of the 'User' row. The 'Add Users' pop-out box appears, use the search bar to find the person who has the authority to review the milestone.

Select the checkbox against their name and then select the tick at the bottom

of the pop-out box to save your selection.

Step 3.

In the 'Notes' section, add any notes as necessary and then click 'Save'.

Step 4.

Select 'View User Decision' and the 'User Decisions' pop-out box appears on the right-hand side of the screen.

Select your name and the decision drop-down menu will appear.
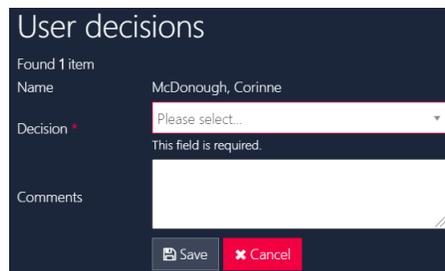
Choose from the following decisions:

❖ Approved – No further action is required
❖ More Information Required – Action is required from the applicant.

A comment needs to be added for a 'More Information Required' this will be pulled through to the email. Once necessary comments have been added, click 'Save'.

Step 5.

The milestone will now be in the status

of 'Revision' and is with the applicant for editing, or 'Achieved'

Manually creating a Milestone

Research Office can create any type of milestone as required.

Step 1.

Select the SSA Project and click 'Milestones'

Step 2.

Select 'Edit' from the right-hand side menu and then select '+ Add milestone' under Milestone summary'.

Step 3.

Fill in the details as per below;

Title: Normally the same at the type but you can add additional detail here
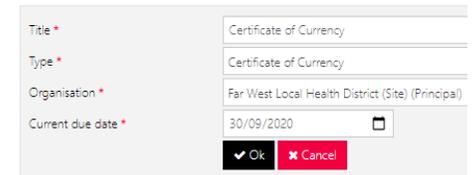
Type: Select from dropdown

Organisation: Auto populates

Current due date: Add due date

Step 4.

Click 'Ok' and then 'Save' on the right-hand side menu.

The new milestone will now appear in the Milestones list for the researcher.