Submitting a governance milestone

Types of governance milestones

The following governance milestones are processed via Research GEMS.

❖ **First patient in:** Date the first patient or participant was enrolled into a clinical trial. The first patient in data is collected for SA metrics.

❖ **Progress report – external HREC:** Where ethics is being managed in another jurisdiction ([National Mutual Acceptance](#) projects), the external HREC approved annual progress reports must be submitted to the site/s.

❖ **Clinical trials data collection:** Annual data collection for clinical trials conducted within SA Health for the preceding financial year.

❖ **Certificate of Currency:** Insurance certificates need to be updated annually to ensure consistent insurance coverage for the life of the project. See user guide Submitting a certificate of currency milestone for further information.

When the ethics application is in GEMS, there is no governance milestone for progress reports. This is submitted and reviewed by the HREC/ Executive Officer and once approved, is shared with each associated site in GEMS. However, a RGO may request further information and the principal investigator (PI) will be notified. See user guide '[Submitting a progress report or final report](#).'

Who should submit governance milestones?

The principal investigator (PI) has overall responsibility of the study at the site and can share access to team members to assist in the completion and submission of governance milestones.

See user guide [Sharing access to applications and projects](#) for further information.

How does it work in GEMS? Top 5 milestones and report forms
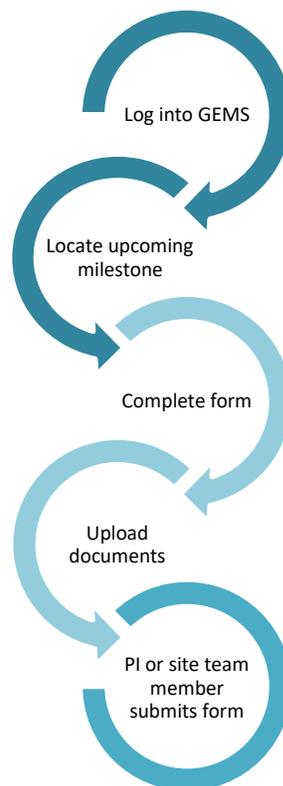
The top five upcoming, due or overdue milestones will appear on the right-hand side of your GEMS homepage.

Select the milestone and you will be taken directly to the milestone's report form. When the milestone has been processed/noted it will no longer appear in this list.

All milestones can be found from within the site-specific assessment (SSA) project. Locate the study project from the 'Projects' icon and click on the required project identifier. You will see the associated SSAs.

Click on the relevant SSA row and select 'Project Information.' Click on the 'Milestones' tab to locate all the milestone report forms.

Submitting First Patient In

Step 1. Locate the milestone
Open the first patient in milestone report form under 'Top 5 Milestones' or from within the SSA project.

Step 2. Clinical trial first participant enrolled
Provide the date the first participant was enrolled at the site.
If no participant enrolment has occurred within 40 days, select 'Not yet enrolled at site' followed by a valid reason/s from the dropdown list.

Step 3. Enrolments targets
Enter the targeted number of participants, minimum and maximum enrolment target numbers per CTRA.

Step 4. Trial registry
If your study is an investigator initiated clinical trial you will be asked to enter the details of where the trial has been registered.

Step 5. Declaration
The PI, delegate or any person with edit access will be able to submit the

milestone report by clicking 'submit' and the status of the milestone will change to

🔵 Received

When the first patient in report has been acknowledged by the RGO, the status of the milestone will change to

🟢 Achieved

The PI and relevant team member/s will receive an email notification.

Submitting progress reports – external HREC

Progress Report – external HREC refers to progress reports where ethics is managed in another jurisdiction. These milestones are manually created by the RGO, so they may not have the same wording as described in this document.

Step 1. Locate the milestone
Open the progress report – external HREC milestone report form under 'Top 5 Milestones' or from within the SSA project.

Step 2. Project details
Ensure the study type is correct as additional questions are generated based off this. If the study type is incorrect, you will need to contact the relevant local research office to have the study type classification changed**.**

Specify if you are submitting the report for all sites listed in GEMS by selecting 'Yes' or 'No'.

Select the type of report being submitted: annual report or final report. Depending on the selection, you will be asked to select the status of the study as noted on the approved external HREC report.
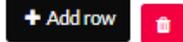
Step 3. SA Site Recruitment/Data/Samples
Answer each question and progress to the next section.

Step 4. Ethics document upload
Upload the approved external HREC report and any other supporting documents.

Use the 'Add row' button to add further rows and the trashcan icon to remove rows.

+ Add row 🗑️

Document type: Select as appropriate.
Document descriptor: Ensure it is clear and descriptive.
Document version and document date: As listed on the document. If there is no version or date, then enter version 0 and the date the milestone report is being submitted.

DO NOT upload amended documents to be reviewed by the RGO. Follow instructions in user guide '[Site amendment – completing and submitting](#)' to complete a general amendment form to submit concurrently with this form.

Step 5. Declaration
The PI, delegate or any person with edit access will be able to submit the milestone report by clicking 'submit' and the status of the milestone will change to

🟢 Achieved

The PI and relevant team member/s will receive a notification email.

The RGO may send an email to request more information, if required.

Submitting clinical trials data collection

Step 1. Locate the milestone
Open the clinical trials data collection milestone report form under 'Top 5 Milestones' or from within the SSA project.

Step 2. Project information
The project information section will automatically populate information that is already available in the system.

Step 3. Site information
Provide the site-specific recruitment and financial information for the preceding financial year of the study.

Use the 'Add row' button to add funding source details. **+ Add row**

Step 4. Declaration

The PI, delegate or any person with edit access will be able to submit the milestone report by clicking 'submit' and the status of the milestone will change to

🟢 Achieved

There is no acknowledgement receipt email for this milestone.

Health
Department for
Health and Wellbeing
Government of South Australia

Version 3.0 27 March 2025

Page 2