

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 5.
- ❖ **Certificate of currency:** Evidence for current professional indemnity and products liability policy/s, or equivalent, and must include clinical trials cover.
- ❖ **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.

When ethics is in GEMS, there is no governance milestone for progress reports. This is reviewed by ethics 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.](#)'

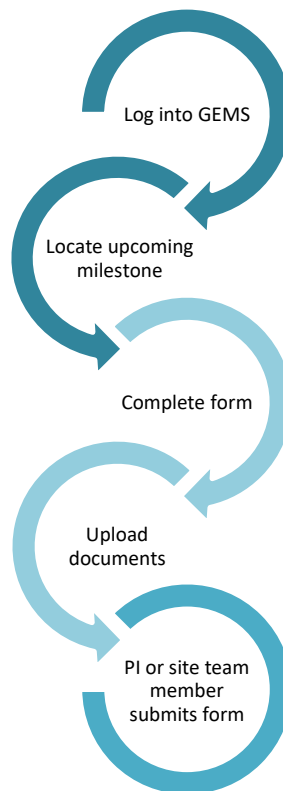
Who should submit governance milestones?

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 in the right-hand side of your GEMS homepage.

📍 **Top 5 milestones due**

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.

Applications Details Forms Milestones

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.

Not yet enrolled at site

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 certificate of currency (CoC)**Step 1. Locate the milestone**

Open the CoC milestone report form under 'Top 5 Milestones' or from within the SSA project.

Step 2. Clinical trial milestone – Certificate of currency

All approved sites in GEMS will be listed. Enter the start and end date of the insurance.

Provide the CoC under 'document upload.'


Type: 'Certificate of currency of insurance' is automatically listed and cannot be edited.

Description: Ensure it is clear and descriptive as this is what will appear on your decision notification.


Document version and document date: As listed on the document. If there is no version or date, then add version 0 and the date the milestone report is being submitted.

Step 3. 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 CoC milestone 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.

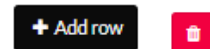
Step 3. SA Site**Recruitment/Data/Samples**

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.



Document type: Select as appropriate.


Document descriptor: Ensure it is clear and descriptive as this is what will appear on your decision notification.

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.

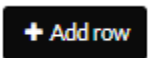
Step 2. Project information

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.



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.