

Submitting a Governance Milestone

Types of Governance Milestones

The following Governance milestones are processed via REGIS

- ❖ **First Patient In:** Date the first patient or participant was enrolled into a clinical trial, consented and screened with eligibility verified. The First Patient In data is collected for the NSW metrics 5.
- ❖ **Certificate of Currency:** Must be submitted that evidences current professional indemnity and products liability policy(s), or equivalent, and must include clinical trials cover.
- ❖ **Progress Report – External HREC:** Where Ethics is outside of REIGS and is being managed in another jurisdiction, the HREC approved annual progress reports must be submitted to the sites.

*Note: When Ethics is in REGIS, a governance milestone is **not created** for a progress report. When approved/achieved by Ethics, it is shared with each site in REGIS and if the RGO requires further information, the PI will be notified.*

Who has the responsibility and should submit the milestones?

The Principal Investigator (PI) has the overall responsibility of the study at the site and is currently the only person who can submit the Certificate of Currency (CoC) and Progress Report – External HREC.

The **First Patient In** milestone can be delegated to any team member who has being given edit access to the STE.

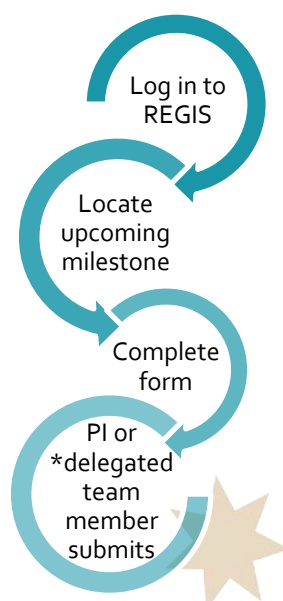
Top 5 Milestones

📍 Top 5 milestones due

On the right-hand side of your homepage is where you can locate the 5 upcoming, due or overdue milestones and the number of days remaining before the due date or the number of days it is overdue.

When the milestone has been processed/noted it will no longer appear in this list.

How does it work in REGIS



Submitting First Patient In

Step 1

You can locate the First Patient In milestone from your homepage under 'Top 5 Milestones', select the milestone and you are brought to the 'First Patient In' page 'Milestone details' section. Select 'Submit Report'.

To access the milestone from within the STE Project, select the 3 vertical dots against the STE identifier, select 'Project Information' and then 'Milestones' from the left-hand menu. Select 'Submit Report'.

Step 3

Clinical Trial First Participant Enrolled Report

Provide the date first participant was enrolled at site.

Step 4

Enrollments targets

Entre the targeted number of participants, minimum and maximum enrollment target numbers per CTRA.

Tip: Click on the help text icon for question specific guidance.

Step 5

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 6

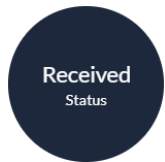
Declaration

If you are the PI or have been delegated to submit the milestone report by the PI, click 'Submit'.

If you are not the PI or do not have access to submit the milestone report, save your progress by selecting the save icon in the top right-hand corner.

Notify the PI that the milestone report can now be submitted.

Step 6



● Received

The First Patient In milestone report is submitted to the Research Governance Office (RGO) when the status of the milestone report changes to

'Received'.

You will be notified via a system generated email when the First Patient In milestone report has been noted.

What if enrollment has not occurred within 40 days?

Step 1

Clinical Trial First Participant Enrolled Report

If no patient or participant enrollment has occurred within 40 days, select the 'Not yet enrolled at site' button.

Not yet enrolled at site

Step 2

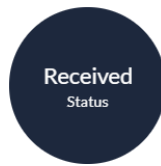
Select a valid reason for there being no enrollment within 40 days

Note: You can select multiple options by clicking the checkbox against the reason.

- ❖ Closed to enrollment / Terminated by sponsor before 40 days
- ❖ Significant sponsor-related delay in Site Activation
- ❖ Other, please describe

If 'Other, please describe' is selected a large free text box will appear which requires information to be provided.

Complete **Steps 4-5**.



● Received

The First Patient In milestone report is submitted to the Research Governance Office (RGO) when the status of the milestone report changes to 'Received'.

The Research Office will not acknowledge receipt of this milestone.

Submitting Certificate of Currency (CoC)

Step 1

You can locate the Certificate of Currency milestone from your homepage under 'Top 5 Milestones', select the milestone and you are brought to the 'Certificate of Currency' page 'Milestone details' section. Select 'Submit Report'.

To access the milestone from within the STE Project, select the 3 vertical dots against the STE identifier, select 'Project Information' and then 'Milestones' from the left-hand menu.

Step 2

Clinical Trial Milestone – Certificate of Currency

All approved sites in REGIS will be listed, enter the start and end date of the insurance.

Add the CoC in the 'Document Upload' row.

Type: Automatically listed as 'Certificate of Currency of Insurance' and cannot be edited.

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

Document Version: As listed on the document, if no version is listed then list 0.

Document Date: Listed on document.

TIP: You can duplicate rows by clicking the checkbox against a row and then selecting the duplicate sign



Step 5

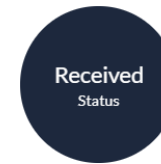
Declaration

If you are the PI, click 'Submit'.

If you are not the PI, save your progress by selecting the save icon in the top right-hand corner.

Notify the PI that the milestone report can now be submitted.

Step 6



● Received

The Certificate of Currency milestone is submitted to the Research Governance Office (RGO) when the status of the milestone report changes to 'Received'.

You will be notified via a system generated email when the Certificate of Currency milestone has been noted.

Submitting Progress Report – External HREC

Note: Progress Report – External HREC refers to progress reports where ethics is outside of REIGS. These milestones are manually created by the Research Governance Office so they may not be worded the same as described in this document.

Step 1


You can locate the Progress Report – External HREC milestone from your homepage under 'Top 5 Milestones', select the milestone and you are brought to the 'Progress Report – External HREC' page 'Milestone details' section. Select 'Submit Report'.

To access the milestone from within the STE Project, select the 3 vertical dots against the STE identifier, select 'Project Information' and then 'Milestones from the right-hand menu. Click 'Submit Report'.

Step 2

Project Details

Ensure that the study type is correct as additional questions are generated based off this. If the study type is incorrect then you will need to contact your local research office to have the study type classification changed.

Is the study type correct? 

Yes: disregard message and progress

No: please contact the research office and request the study type classification be changed. Click on the helptext icon above for a list of study types and definitions.

Seeing this message will not stop the submission of this form, however forms submitted with incorrect study types may cause the form to be unsubmitted.

Select if you are submitting the report for all sites listed in REGIS 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 report i.e. In Progress, Completed, Terminated etc.

Step 3 Recruitment/Data/Samples

Answer each question and progress to the next section.

Step 4 Ethics Document Upload

Upload the HREC noted annual report and any other supporting documents in this section.


  Use the plus '+' icon to add further rows and the minus '-' icon to remove rows.

Document Type: Select as appropriate i.e. Annual Safety Report, Milestone Report etc.

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

Document Version: As listed on the document, if no version is listed then list 0.

Document Date: Listed on document.

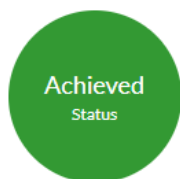
TIP: You can duplicate rows by clicking the checkbox against a row and then selecting the duplicate sign 


Step 5 Declaration

If you are the PI, click 'Submit'.

If you are not the PI, save your progress by selecting the save icon in the top right-hand corner and notify the PI that the Progress Report – External HREC milestone can now be submitted.

Step 6



 **Achieved**

The Progress Report – External HREC milestone is submitted to the Research Governance Office (RGO) and the status of the milestone changes to 'Achieved'.

You will only be notified via a system generated email if more information is required.