Submitting a Governance Milestone

Types of Governance Milestones

The following Governance milestones are processed via REGIS:

❖ **Progress Report – External HREC:** Where Ethics is outside of REGIS and is being managed in another jurisdiction, the HREC approved annual progress reports must be submitted to the sites.

❖ **First Patient In (Clinical Trial Only):** 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 (Clinical Trial Only):** Must be submitted that evidences current professional indemnity and products liability policy(s), or equivalent, and must include clinical trials cover.

*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. If the RGO requires further information, the PI will be notified.*

Who Has the Responsibility & Should Submit the Milestones?

The Principal Investigator (PI) has the overall responsibility of the study at their site. The PI and their delegate(s) can submit the Progress Report – External HREC. The **First Patient In** and **Certificate of Currency (CoC)** milestones can be submitted by the PI, delegate(s) or anyone with *'Edit' access to the STE project.

Top 5 Milestones

📍 Top 5 milestones due

On the right-hand side of your homepage, you can locate the five 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?

Log in to REGIS

Locate upcoming milestone

Complete form

PI, delegate or anyone with *'edit' access submits

Submitting First Patient In

Step 1
This milestone is only created when the study is a Clinical Trial.

You can locate the First Patient In milestone from your homepage under 'Top 5 Milestones'. Click on the milestone and you are brought directly into the form to complete the milestone.

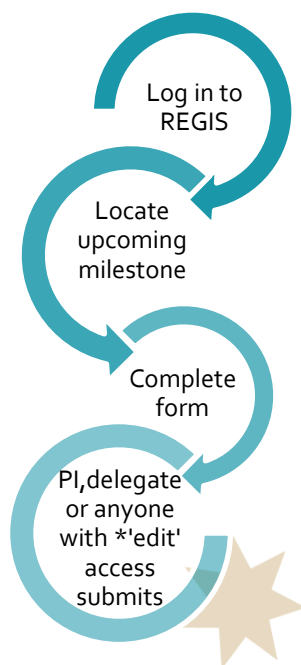Applications   Details   Forms   **Milestones**

To access the milestone from within the STE Project:

On your homepage, at the top of the screen, locate the study via 'Projects', select the project, select the STE identifier and navigate to Milestones.

Locate the First Patient in Milestone

IDENTIFIER	MILESTONE TITLE
2021/STE01814	First Pt
2021/STE01814	Certificate of Currency
2021/STE01814	HREC approved annual report

Step 3
Clinical Trial First Participant Enrolled Report
Provide the date first participant was enrolled at site.

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

Step 4
Enrollments targets
Enter the targeted number of participants, minimum and maximum enrollment target numbers per CTRA.

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
The PI, their delegate(s) and anyone with edit access can submit the First Patient In milestone.

Step 7
The First Patient In milestone report is submitted to the Research Governance Office (RGO) when the status of the milestone report changes to 'Achieved.

No further action is required. The Research Office will not acknowledge receipt of this milestone.

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**.

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

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'. Click on the milestone and you are brought directly into the form to complete the milestone.

To access the milestone from within the STE Project, click the PID, then click the STE and navigate to Milestones.

| Applications | Details | Forms | **Milestones** |

Locate the Certificate of Currency milestone.

IDENTIFIER	MILESTONE TITLE
2021/STE01814	📄 First Pt
2021/STE01814	📄 Certificate of Currency
2021/STE01814	📄 HREC approved annual report

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.

Step 5
Declaration
The PI, their delegate(s) and anyone with edit access can submit the Certificate of Currency milestone.

Step 6
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.

🔵 Received

If there are multiple NSW approved sites all RGO and PIs will receive the notification. The Certificate of Currency does not need to be individually submitted to multiple sites.

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 titled the same as described in this document.

Step 1
Locate the Progress Report – External HREC milestone from your homepage under 'Top 5 Milestones', or STE 'Milestone' section.

To access the milestone from within the STE Project, select the STE identifier and then Milestones

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.

REGIS allows for a single submission to all NSW authorised sites. If you are submitting the report for all sites listed in REGIS selecting 'Yes'.

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.

Click Add Another for a row to apper.

Document Type: Select as appropriate

Document Descriptor: Ensure it is clear, descriptive and includes the version and date, if they exist, as this is what will appear on your decision notification.

Document Descriptor *

Step 5
Declaration
The PI or their delegate(s) can submit the Progress Report – External HREC milestone report. If you do not have access to submit, save your progress by selecting the save icon in the top right-hand corner and notify the PI that it is ready for submission.

Step 6
The Progress Report – External HREC milestone is submitted to the Research Governance Office (RGO) and the status of the milestone changes to 'Achieved'.

● Achieved

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