

RESEARCH GOVERNANCE CLINICAL TRIAL START-UP REPORT



It is a condition of site authorisation that this report be submitted by 60 days post-authorisation even if no (zero) patients are enrolled. Submit to SCHN-Governance@health.nsw.gov.au anytime up to 60 days post-authorisation, from enrolment of your first participant, or after 40 calendar days of site-authorisation, whichever occurs first. This data will enable the Chief Executive to provide institutional data to the Office for Health and Medical Research.

HREC Reference Number:

SSA Reference Number:

Project Title:

Site:	CHW	SCH	Other	Site name
--------------	-----	-----	-------	-----------

Site Authorisation Date:

**Clinical Trial
Registration Number:**

Date of Report:

Report completed by: *Name and study role*

Site Activation Date:

Sponsor has notified the site that clinical activities, including recruitment, can commence. The date of SSA Authorisation for Investigator Initiated Studies.

What is the recruitment target?

As agreed per executed contract

Date 1st Patient Enrolled:

Patient consented, screened and eligibility confirmed. Often date of randomisation (where applicable).

**Number of participants
enrolled to date:**

Complete even if zero patients enrolled

Did you enrol your first participant within 40 days of site authorisation?

Yes.

No. Please select one valid reason below:

Study closed to enrolment / recruitment by sponsor before 40 days from Site Authorisation

Significant sponsor-related delay in Site Activation.

e.g. overseas sponsor waiting for multiple site activation to plan travel to Australia; sponsor waiting protocol amendment before activation; sponsor delay in drug shipment to site; unknown reason for delay by sponsor.

Other. Please specify details: