

National Aggregate Statistics: Definitions

National Clinical Trial Activity

^[L]_{SEP} **Metric 1: Number of new trials per trial phase (by trial type ‘medicine’ only)**

FTIH/FTIP, Phase 1, Phase 2, Phase 3, Phase 4, Total

Metric 1a: Number of new clinical trials per sponsor type

Collaborative Group, Commercially Sponsored, Institution, Investigator Initiated Group, Other, Total

Regulatory Timelines - total^[L]_{SEP}

Metric 2: Overall study start-up timeline (regulatory timeline) – Without Clock^[L]_{SEP}

Time in days from Ethics Cut-off Date/Submission Closing Date to date of First SSA/Site Authorisation Date, ‘**Without clock**’ operating.

Metric 2 provides a proxy for study start up timelines by measuring the timeline (i.e., time in days) for the two mandatory approval/regulatory processes for clinical trials in Australia: from ethics closing date to date of first SSA/site authorisation.

This metric does not measure intervals when the clock is stopped and re-started during the review (i.e., where there is a request for information from investigator/trial coordinator/sponsor/CROs), so it is a measure of **total time**.

^[L]_{SEP} **Metric 3: Ethics and SSA/site assessment approval timeline – With Clock**

Time in days from Ethics Cut-off Date/Submission Closing Date to date of First SSA/Site Authorisation Date, ‘**With clock**’ operating.

Metric 3 also measures approximate overall study start up, same as Metric 2, but includes an administrative clock which distinguishes the time spent by the administering organisation and the investigator/trial coordinator/sponsor/CRO.

This metric is “with clock”, so the clock is used to calculate HREC time only - intervals are deducted when the responsibility for the ethics application is with the investigator/trial coordinator, sponsor/CRO. Therefore, this metric is a measure of **administration time**.

Metric 4a: Ethics approval timeline - Without Clock

Time in days from Ethics Cut-off Date/Submission Closing Date to the Ethics Approval Clock Stop Date, ‘**Without clock**’ operating.

This metric covers timepoints including: submission closing date, validation, HREC review, request for further information, responses from applicants, and final ethics approval.

This metric does not measure any intervals when the clock is stopped and re-started during ethics review because there is a request for information from investigator/trial coordinator/sponsor/CROs, it is a measure of **total time**.

Metric 4b: Ethics approval timeline - With Clock

Time in days from Ethics Cut-off Date/Submission Closing Date to Ethics Approval Clock Stop Date, **'with clock'** operating.

This metric measures the Ethics Submission and approval process using the same as the information in Metric 4a, but it distinguishes the time spent by the administering organisation and the investigator/trial coordinator/sponsor/CRO.

This metric covers timepoints including: submission closing date, validation, HREC review, request for further information, responses from applicants, and final ethics approval. It allows measurement and deduction of the time (in days) between request and receipt of further information from investigator/trial coordinator/sponsor/CRO and these intervals are deducted from the total time. Therefore this is a measure of **administration time**.

Metric 5a: SSA/site authorisation timeline from HREC approval date - Without Clock

Time in Days from Date of HREC approval to SSA Authorisation Date, **'Without clock'**

This metric covers timepoints including: submission, validation, Research Governance Officer (RGO) review, request for further information, responses from applicants, CEO/delegation decision, and SSA/site assessment/research governance authorisation.

The metric measures the total timeline (ie. **'Without Clock'** only), as there is no defined start point/submission date for SSA activities. This measures the **total time** taken for SSA/site submission and assessment.

For this metric, SSA validation date is defined as the first date that the application appears in electronic information systems used to document SSA applications.

Metric 5b: SSA/site authorisation timeline from SSA Validation Date - Without Clock

Time in Days from date of SSA Validation to SSA approval, **'Without Clock'** operating.

This metric covers timepoints including: submission, validation, Research Governance Officer (RGO) review, request for further information, responses from applicants, CEO/delegation decision, and SSA/site assessment/research governance authorisation.

The metric measures the total timeline (ie. **'Without Clock'** only), as there is no defined start point/submission date for SSA activities. This measures the **total time** taken for SSA/site assessment alone.

For this metric, SSA validation date is defined as the first date that the application appears in electronic information systems used to document SSA applications.

Recruitment/Investment

Metric 6: Trial Recruitment Actual/Planned

Actual and expected number of participants recruited to a clinical trial

Total expected and total actual number of participants recruited to a clinical trial by trial phase and sponsor type for the trial, jurisdiction, and nationally for the reporting period.

Metric 7: Site Recruitment: Actual/Planned^{SEP}

Actual and expected number of participants recruited to a clinical trial at a specific site.

Total expected and total actual number of participants recruited to a clinical trial by trial phase and sponsor type for the trial, trial unit, and hospital for the reporting period.

Metric 8: Total inbound (internal and external) investment annually (FY) Actual/Planned

Total inbound investment (internal and external) annually by trial, trial unit, hospital, jurisdiction and nationally.

Calculation: (targeted number participants at this site) x (per participant payment) AND (pharmacy investment amount) AND (pathology investment amount) AND (total any other income).