Definitions for Service Agreement Indicators

2017/18

INDICATOR: MS5301, MS5302	Participants enrolled to commercial clinical trial projects:
Previous ID:	• As a proportion of those initially agreed to be enrolled per the Clinical Trial Research Agreement minimum target (%) *(MS5301)* • First participant enrolled by the site within 40 calendar days of site authorisation (%)*(MS5302)*
Service Agreement Type	Monitoring Measure
Framework Strategy	Strategy 5: Support and Harness Health & Medical Research and Innovation
Framework Objective	5.3 (Make NSW a global leader in clinical trials)
Status	Final
Version number	1.0
Scope	
Goal	• To increase the number of commercial trials that achieve or surpass their enrolment target. • To reduce the time taken to enroll the first participant into commercial trials conducted in NSW.
Desired outcome	
Primary point of collection	
Data Collection Source/System	AU RED; then REGIS when implemented
Primary data source for analysis	AU RED; then REGIS when implemented
Indicator definition	MS5301: The proportion of commercial clinical trials (excluding LNR) closed to enrolment at the site within the reporting period, that reached or surpassed their minimum enrolment target at study closure. MS5302: The proportion of commercial clinical trials (excluding LNR) authorised within the reporting period with at least one participant enrolled by Day 40 post Site Specific Authorisation.
Numerator	
Numerator definition	MS5301: Total number of commercial clinical trials (excluding LNR) that closed to enrolment at the site within the reporting period, that reached or surpassed their enrolment target at study closure. MS5302: Total number of commercial clinical trials (excluding LNR) authorised within the reporting period with at least one participant enrolled by Day 40 post Site Specific Authorisation.
Numerator source	AU RED; then REGIS when implemented
Numerator availability	
Denominator	
Denominator definition	MS5301: Total number of commercial clinical trials (excluding LNR) closed to enrolment at the site within the reporting period. MS5302: Total number of commercial clinical trials (excluding LNR) authorised within the reporting period.

Denominator source	AU RED; then REGIS when implemented
Denominator availability	

Inclusions

MS5301:

- Study Type = Clinical trial (other); Clinical trial of a drug; Clinical trial of a device; Clinical trial of a drug and device; First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical trial – drug; First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical trial – device; First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical trial – drug and device.
- LNR = No
- Major Sponsor Type = Commercially Sponsored
- Application Type = Site Specific Assessment
- Current Decision = Authorised; authorised with conditions; further information response authorised.
- Study State = Closed to enrolment at site

MS5302:

- Study Type = Clinical trial (other); Clinical trial of a drug; Clinical trial of a device; Clinical trial of a drug and device; First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical trial – drug; First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical trial – device; First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical trial – drug and device.
- LNR = No
- Major Sponsor Type = Commercially Sponsored
- Application Type = Site Specific Assessment
- Current Decision = Authorised; authorised with conditions; further information response authorised.

Exclusions

MS5301:

- Study Type = Clinical research; Health Research/ Social Science; Other (please state)
- LNR = Yes
- Major Sponsor Type = Collaborative Group; Investigator Initiated Group; Institution; Other
- Application Type = Application – Single Site; Application – Multi Site
- Current Decision = Invalid application; not authorised; Request for further information/ modification; not requiring review by Research Organisation; further information response not authorised; further information response not complete
- Study State = all except “closed to enrolment at site.” (Study state may have been subsequently changed since it was set to “closed to enrolment at site”. Data will be culled for all studies wherein Study State was designated “closed to enrolment at site” within the reporting period.)

MS5302:

- Study Type = Clinical research; Health Research/ Social Science; Other (please state)
- LNR = Yes
- Major Sponsor Type = Collaborative Group; Investigator Initiated Group; Institution; Other
- Application Type = Application – Single Site; Application – Multi Site
- Current Decision = Invalid application; not authorised; Request for further information/ modification; not requiring review by Research Organisation;

	further information response not authorised; further information response not complete
Targets	N/A
Context	
Related Policies/ Programs	http://www.health.nsw.gov.au/ethics/Documents/metrics-manual.pdf
Useable data available from	
Frequency of Reporting	Annually
Time lag to available data	
Business owners	Office for Health and Medical Research
Contact - Policy	Executive Director, Office for Health and Medical Research
Contact - Data	Executive Director, Office for Health and Medical Research
Representation	
Data type	Numeric
Form	Number, presented as a percentage (%)
Representational layout	NNN.N
Minimum size	3
Maximum size	5
Data domain	N/A
Date effective	
Related National Indicators	
Indicator	
Source	