COVID-19 Client Bulletin

Status as at: 5th April 2022

Australia COVID-19 Snapshot

	Australia		United States		tates
	#	Δ^{1}		#	Δ^{1}
Confirmed Cases	4,847,725	159%		81.9m	+21%
Deaths	6,462	133%		1,009,390	+15%
Deaths per 1M	248	132%		3,018	+15%
Testing rate per 1M	2,583,233	-		2,952,541	-
Population with at least one vaccination	~86%			~77%	

Australia: New and cumulative COVID-19 cases by notification date

N NOVOTECH

The Asia Pacific CRO



(1) change versus previous month

Australia Clinical Trial Insights

Feasibility	Majority of sites continue to be very interested in new studies.
Ethics and Governance	 Review and approval of clinical trials are continuing as scheduled. All submissions completed electronically, and legal documents e-signed.
Recruitment	 Most Top 10 sites are open for recruitment with some exceptions and for SIVs for new studies, some of which are being conducted as remote visits.
Participant visits	 Most Top 10 sites are open to subject visits with ongoing social distancing measures. Sites continue to assess potential for study visits/specific assessments to be completed closer to the participant home to ensure all protocol requirements are met (e.g., local pathology and imaging) including Telehealth and home nursing options.
Monitoring	 90% of the Top 10 sites are open to onsite or remote monitoring visits. Some sites are requiring vaccination status and/or a negative Rapid Antigen test prior to being able to attend site. Novotech is deploying our regionally based CRA teams to ensure continuity with monitoring if local monitors are mandated by the sites.
IP Supply and delivery	 Passenger jet volume at normal levels with normal operation of air couriers and local delivery. Contingency in place to proactively ensure sufficient IP stock in the country to mitigate any delays with IP supply chain, if necessary. Multiple vendors available for Direct to Patient IP delivery and home IP administration, where appropriate.
General	 Omicron case numbers and hospitalisation across Australia have increased since January. Currently >450,000 active cases across AU. Flights within Australia are increasing, and we are able to travel across state borders. International borders opening for fully vaccinated. There are currently no lockdowns. Australian Health Authority has approved the Pfizer, AstraZeneca and Moderna vaccines for deployment as per phased Vaccination Rollout Plan. Novavax (first protein vaccine) is now registered and available for people aged 18 years and over with no previous vaccination. >95% of people aged 16 and over are fully vaccinated, with >61% boosters administered (16+). Electronic signature widely accepted. Sites, Industry, Health Authority and National HRECs coordinating activities to ensure subject safety and trial continuity. 100% of Novotech staff can work remotely with office access if required. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation.
COVID-19	High levels of investigator interest, institutional support, and acceleration of processes from ethics/regulatory authorities
Trials	Final protocol to site activation estimated to be 3-4 weeks.

Top 10 sites: High level status

	Ethics/Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
Westmead Hospital	Available	Available (remote)	Available (exceptions)	Available	Remote visits	Expedited
Monash Hospital	Available	Available (remote)	Available	Available	Remote visits	Expedited
The Royal Melbourne	Available	Available	Available	Available	Available onsite	Expedited
Nucleus Network Ltd	Available	Available	Available	Available	Available onsite	Only vaccine trials expedited
Royal Adelaide Hospital	Available	Available (remote)	Available	Available	Available onsite (exceptions)	Expedited
The Alfred Hospital	Available	Available	Available (except for <mark>respirato</mark> ry)	Available (except for r <mark>espiratory</mark>)	Available onsite or remote visits	Expedited
Austin Hospital	Available	Available (remote)	Available	Available	Remote visits	Requires exec approval
Royal Prince Alfred Hospital	Available	Available (remote)	Available	Available	Remote visits	Expedited
Linear Clinical Research	Available	Available (remote)	Available	Available	Available onsite or remote	Only vaccine trials expedited
St Vincent's (Melbourne)	Available	Available (remote)	Available	Remote visits	Available onsite or remote visits	Expedited

Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.org, health.gov.au