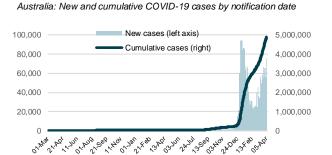


COVID 10

Australia COVID-19 Snapshot

	Austra	alia	United S	tates
	#	Δ1	#	Δ1
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%	



(1) change versus previous month

Australia Clinical Trial Insights

Feasibility Majority of sites continue to be very interested in new studies. Ethics and Review and approval of clinical trials are continuing as scheduled. Governance All submissions completed electronically, and legal documents e-signed. 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 Recruitment Most Top 10 sites are open to subject visits with ongoing social distancing measures. **Participant** Sites continue to assess potential for study visits/specific assessments to be completed closer to the participant home to ensure all protocol visits requirements are met (e.g., local pathology and imaging) including Telehealth and home nursing options. 90% of the Top 10 sites are open to onsite or remote monitoring visits. **Monitoring** 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. Passenger jet volume at normal levels with normal operation of air couriers and local delivery. IP Supply and Contingency in place to proactively ensure sufficient IP stock in the country to mitigate any delays with IP supply chain, if necessary. delivery Multiple vendors available for Direct to Patient IP delivery and home IP administration, where appropriate 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. General >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

Top 10 sites: High level status

COVID-19

Trials

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	trials
		Available	Available		5	E 1971
Westmead Hospital	Available	(remote)	(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 respiratory)	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

High levels of investigator interest, institutional support, and acceleration of processes from ethics/regulatory authorities

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

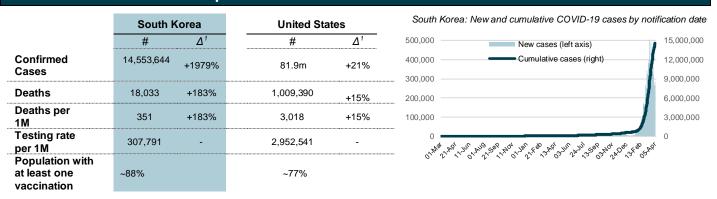
Final protocol to site activation estimated to be 3-4 weeks.

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

Status as at: 5th April 2022



South Korea COVID-19 Snapshot



(1) change versus previous month

South Korea Clinical Trial Insights

oodin Rorca	
Feasibility	Majority of sites continue to be very interested in new studies. Recent Omicron variance dominant circumstances, delayed response from site captured due to COVID-19 infection from site staffs.
Ethics and Governance	Review and approval of non-COVID-19 clinical trials are continuing as scheduled.
Recruitment	Clinical trial sites are open, and recruitment is ongoing at all trial sites.
Participant visits	Subject visits are available at all sites with social distancing measures implemented.
Monitoring	Monitoring visits are limited in a few top sites, very competitive monitoring room booking found with limited capacity.
IP Supply and delivery	 Normal operation of air couriers and local delivery. Contingency in place ensure sufficient IP stock in the country to mitigate any delays with international IP supply chain. Multiple vendors available for direct to patient IP delivery as per MFDS guideline.
General	 Electronic signature accepted. Sites, Industry, Health Authority and ECs 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 Trials	 The South Korean Ministry of Food and Drug Safety (MFDS) has announced "GO-expedite" program where they are expediting the review process for COVID-19 treatment and vaccine trials with specific timelines. A Novotech client's COVID-19 trial was approved in under 9 days in South Korea. High levels of investigator interest and institutional support to participate in COVID-19 trials. Currently there are 75 COVID-19 trials approved in South Korea. Novotech is involved on two of these projects.

• 8 Covid-19 new drug approval by MFDS: 6 vaccines (2 AstraZeneca, Pfizer, Janssen, Moderna, SK Bio), 2 treatments (Gilead, Celltrion).

Top 10 sites: High level status

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID- 19 trials
Asan Medical Center	Available	On site or Remote	Available	Available	Available	Expedited
Samsung Medical Center	Available	On site or Remote	Available	Available	Available (limited seats)	Expedited
Seoul National University Hospital	Available	On site or Remote	Available	Available	Available	Expedited
Seoul National University Bundang Hospital	Available	On site or Remote	Available	Available	Available	Expedited
Severance Hospital, Yonsei University Health System	Available	On site or Remote	Available	Available	Available	Expedited
The Catholic University of Korea Seoul St.Mary's Hospital	Available	On site or Remote	Available	Available	Available (limited seats)	Expedited
Pusan National University Hospital	Available	On site or Remote	Available	Available	Available	Expedited
Gachon University Gil Medical C.	Available	On site or Remote	Available	Available	Available (limited seats)	Expedited
Chonnam National University Hwasun Hospital	Available	On site or Remote	Available	Available	Available (limited seats)	Expedited
The Catholic University of Korea, St. Vincent Hospital	Available	On site or Remote	Available	Available	Available (limited seats)	Expedited

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

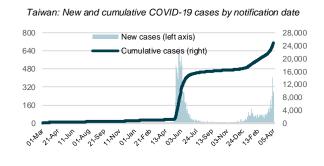
Sources: Worldometer, Ourworldindata.org

Status as at: 5th April 2022



Taiwan COVID-19 Snapshot

	Tai	wan	United S	tates
	#	Δ^1	#	Δ^1
Confirmed Cases	25,225	41%	81.9m	+21%
Deaths	853	-	1,009,390	+15%
Deaths per 1M	36	-	3,018	+15%
Testing rate per 1M	544,143	-	2,952,541	-
Population with at least one vaccination	~82%		~77%	



(1) change versus previous month

Taiwan 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.

Recruitment • Sites are open for recruitment.

Participant visits • Sites are open for subject visits at all sites.

• Negative PCR and rapid test can be waived if fully vaccinated or 3 doses of vaccine over 14 days, applicable for on-site monitoring

Monitoring at most of sites.

Very competitive monitoring room booking found with limited capacity at some sites

IP Supply and delivery • No impact and the IP supply chain is operating with no restrictions.

100% of Novotech staff can work remotely with office access if required.
 State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation.

Electronic signatures are now accepted at some sites, however, will require wet-ink signatures when usual practices resume.

COVID-19 Trials
• High levels of interest, institutional support, and acceleration of processes from ethics/regulatory authorities for COVID-19 trials.

Top 10 sites: High level status

General

National Taiwan University
China Medical University
Chang Gung Memorial Hospital- Linko
Taipei Veterans General
Chang Gung Memorial Hospital Kaohsiung
Kaohsiung Medical University Hospital
Tri-service General Hospital
Chung Shan Medical University Hospital
Changhua Christian Hospital
Chi Mei Medical Center
Taichung Veterans General

Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
Available	Available	Available	Available	Available (PCR test/Rapid test within 3 days)	Expedited
Available	Available	Available	Available	Available	Expedited
Available	Available	Available	Available	Available (PCR test within 3 days)	Expedited
Available	Available	Available	Available	Available	Expedited
Available	Available	Available	Available	Available (PCR test within 3 days)	Expedited
Available	Available	Available	Available	Available (PCR test within 3 days)	Expedited
Available	Available	Available	Available	Available (PCR test/ Rapid test within 3 days)	Expedited
Available	Available	Available	Available	Available	Expedited
Available	Available	Available	Available	Available (PCR/ Rapid test within 3 days)	Expedited
Available	Available	Available	Available	Temporarily not available.	Expedited
Available	Available	Available	Available	Available	Expedited

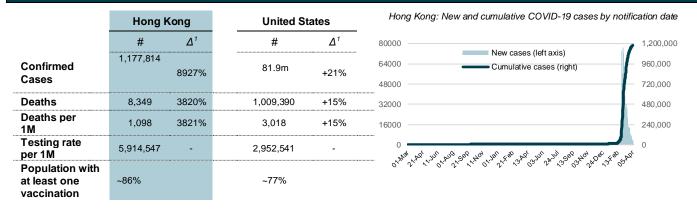
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.org

Status as at: 5th April 2022



Hong Kong COVID-19 Snapshot



⁽¹⁾ change versus previous month

Hong Kong Clinical Trial Insights

5 5	
Feasibility	Majority of sites continue to be very interested in new studies.
Ethics and Governance	Review and approval of non-COVID-19 clinical trials are continuing as scheduled.
Recruitment	Most sites are open for recruitment.
Participant visits	 In public sites, subject visits are normally proceeding with no changes required. There has been limited impact for subjects that reside in China and seen in a few private sites and institutions.
Monitoring	 Most public sites restrict onsite monitoring visits. Private sites normally remain opened. Negative RAT result or full Covid vaccination is required for on-site visit at some public sites. Pregnant visitors are restricted at some public sites.
IP Supply and delivery	No impact and the IP supply chain is operating with no restrictions.
General	 Sites, Industry, Health Authority and ECs coordinating activities 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. DoH approved Pfizer and Sinovac vaccines.
COVID-19 Trials	 Acceleration of processes from ethics/regulatory authorities for COVID-19 trials. Due to the COVID-19 outbreak, investigators are primarily interested in moderate to severe trials. Institution resource is one of the concerns of COVID-19 trials during the peak of outbreak.

Top biotech sites: High level status

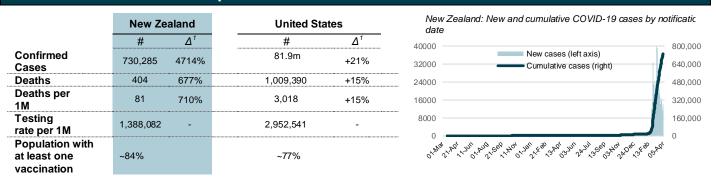
	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
Queen Mary Hospital	Available	Remote	Available (with exception)	Available	Remote	Expedited
Prince of Wales Hospital	Available	Remote	Available	Available	Available onsite/remote	Expedited
Princess Margaret Hospital	Available	Remote	Available	Available	Remote	Expedited
Queen Elizabeth Hospital	Available	Remote	Available	Available	Remote	Expedited
Alice Ho Miu Ling Nethersole Hospital	Available	Remote	Available	Available	Remote	Expedited
Tuen Mun Hospital	Available	Remote	Available	Available	Remote	Expedited
Humanity & Health Clinical Trials Center	Available	Remote	On-hold	Available	Remote	-
Pamela Youde Nethersole Eastern Hospital	Available	Remote	Available	Available	Remote	Expedited
Hong Kong United Oncology Centre	Available	Remote	Available	Available	Available onsite	-
UNIMED Medical Institute	Available	Remote	Available	Available	Available onsite	-

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

Sources: Worldometer, Ourworldindata.org



New Zealand COVID-19 Snapshot



(1) change versus previous month

New Zealand Clinical Trial Insights

Feasibility	Sites continue to be very interested in new studies.
Ethics and Governance	 Review and approval of non-COVID-19 clinical trials are continuing as previously scheduled for majority of sites.
Recruitment	 Sites continue to recruit patients across the country. Experiencing recruitment delays due to COVID-19, staff redeployment and required patient isolations.
Participant visits	Patient visits are ongoing.
Monitoring	 On-site monitoring visits have resumed across New Zealand as we are now in the Traffic Light system. Some sites have moved to removed monitoring.
IP Supply and delivery	 Tight controls at the borders continue. International commercial flights have been decreased; however, logistic companies continue to supply the country. No restrictions on IP supply to sites by the drug depot.
General	 New Zealand is under the Red Light. 13/Apr/2022 vaccinated AUS citizens can enter NZ Most travellers entering NZ can now self-isolate and will no longer need to enter Managed Isolation. Electronic signature widely accepted, now including Indemnities as the need for witness has been removed for the NZACRes template. 100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation. MedSafe has approved the Pfizer, AstraZeneca and Novavax Covid-19 vaccines.

COVID-19 Trials

High levels of investigator interest, institutional support, and acceleration of processes from ethics/regulatory authorities.

Top sites: High level status

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
NZCR (Auckland Clinical Studies)	Available	Available	Available	Available	Available	Expedited
Auckland City Hospital	Available	Available	Available	Available	Available	Expedited
Christchurch Hospital	Available	Available	Available	Available	Available	Expedited
Middlemore Hospital	Available	Available	Available	Available	Available	Expedited
NZCR (Christchurch Clinical Studies Trust)	Available	Available	Available	Available	Available	Expedited
Clinical Trials New Zealand	Available	Available	Available	Available	Available	Expedited
Dunedin Hospital	Available	Available	Available	Available	Available	Expedited
Christchurch Diabetes Centre	Available	Available	Available	Available	Available	Expedited
New Zealand Brain Research Institute	Available	Available	Available	Available(Available	Expedited

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

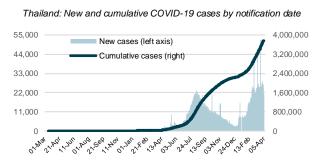
Sources: Worldometer, Ourworldindata.org

Status as at: 5th April 2022



Thailand COVID-19 Snapshot

	Thaila	Thailand		United States		
	#	Δ^1	_	#	Δ^{1}	
Confirmed Cases	3,781,827	62%		81.9m	+21%	
Deaths	25,700	17%		1,009,390	+15%	
Deaths per 1M	367	17%		3,018	+15%	
Testing rate per 1M	246,347	-		2,952,541	-	
Population with at least one vaccination	~80%			~77%		



(1) change versus previous month

Thailand Clinical Trial Insights

Ethics and Governance

Feasibility

- Ethics Committees are accepting new projects online or via a portal as normal. Thai FDA shows some delays in response and approval.
- Recruitment Recruitment is open.
- Participant visits Participant visit has resumed to normal operations.
- Monitoring

 Onsite monitoring visits are open with the need to have negative result of RT-PCR or ATK.
- IP Supply and delivery
- 14-day quarantine is required for international travellers

Sites continue to be very interested in new studies.

- Domestic flights are resumed operations since 1st Sep 2021.
- Marken vendor approved by QA and may be utilised by sites, if required, as a contingency.

General

Novotech office in Bangkok is open with 25% capacity. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation.
 Public COVID-19 vaccine rollout is from June'21 onward and 65% of total population receiving at least 2 -doses. Lockdown and Curfew is lifted since 1Nov.

COVID-19 Trials

HA and EC have an expedited COVID-19 trials review commitment of 8 weeks.

Top sites: High level status

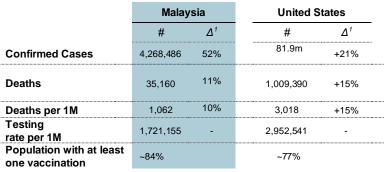
	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
Maharaj Nakorn Chiang Mai Hospital	Available	Available	Available	Available	Available	Expedited
Srinagarind Hospital	Available	Available	Available	Available	Available	Expedited
Siriraj Hospital	Available	Available	Available	Available	Available	Expedited
Songklanagarind Hospital	Available	By video	Available	Available	By video	Expedited
King Chulalongkorn Memorial Hospital	Available	Available	Available	Available	Available	Expedited
Phramongkutklao Hospital	Available	Available	Available	Available	Available	Expedited
Thammasat Hospital	Available	Available	Available	Available	Available	Expedited
Ramathibodi Hospital	Available	Available	Available	Available	Available	Expedited
Rajavithi Hospital	Available	Available	Available	Available	Available	Expedited

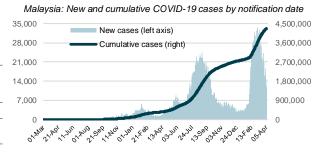
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.org



Malaysia COVID-19 Snapshot





(1) change versus previous month

Malaysia Clinical Trial Insights

Feasibility	Majority of sites continue to be very interested in new studies
Ethics and Governance	 EC and HA review ongoing as per schedule now. An expedited review will be given by EC and HA for these studies under pandemic/epidemic status for public health interests. The timeline for expedited review is 20 working days.
Recruitment	Recruitment is ongoing at sites,
Participant visits	Most sites remain open for subject visits, subject to Principal Investigator's discretion/ Hospital's direction.
Monitoring	 Onsite monitoring visits are now allowed at most sites, Remote monitoring can still be allowed at most sites, with remote SDV limited at certain sites.
IP Supply and delivery	 No restrictions on IP supply to sites by the drug depot. DTP vendor approved by QA and may be utilised by sites, if required, as a contingency.
	The Malaysian government has relaxed COVID −19 rules and SOPs and will transition to endemic phase on 1st April 2022.

General

- Interstate travel now permitted for all regardless of vaccination status
- 100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation.

COVID-19 Trials

- HA and EC expedite COVID-19 trials on a case-by-case basis.
- Currently Malaysia is participating in a few COVID-19 vaccine trials and treatment trials.

Top 10 sites: High level status

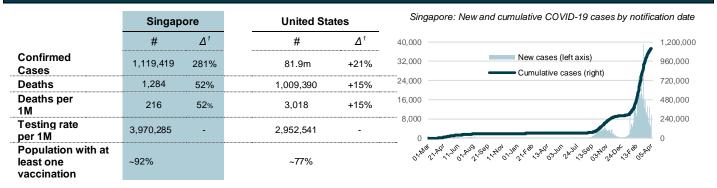
	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
University Malaya Medical C.	Available	Available	Available	Available	On site	Expedited
Hospital Kuala Lumpur	Available	Available	Available	Available	On site	Expedited
Hospital Pulau Pinang	Available	Available	Available	Available	On site	Expedited
Hospital Ampang	Available	Available	Available	Available	On site	Expedited
Hospital Umum Sarawak	Available	Available	Available	Available	On-Site	Expedited
Hospital Raja Perempuan Zainab II	Available	Available	Available	Available	On site	Expedited
Hospital Raja Permaisuri Bainun	Available	Available	Available	Available	On site	Expedited
Hospital Serdang	Available	Available	Available	Available	On Site	Expedited
Hospital Sultan Ismail	Available	Available	Available	Available	On-Site	Expedited
Hospital Tengku Ampuan Afzan	Available	Available	Available	Available	On Site	Expedited

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

Sources: Worldometer, Ourworldindata.org



Singapore COVID-19 Snapshot



(1) change versus previous month

Singapore	e Clinical Trial Insights
Feasibility	Majority of sites continue to be very interested in new studies however some delays in response are expected.
Ethics and Governance	 EC and HA review ongoing as per schedule. Singapore HA has released guidance on conduct of clinical trials in relation to the COVID-19 situation.
Recruitment	Recruitment is resumed for all sites.
Participant visits	 Subject visits ongoing per normal. If remote study visits are to be implemented, this must be notified to HA prior to implementation.
Monitoring	 On-site monitoring visits are allowed, monitors must be fully vaccinated, with a negative Antigen Rapid Test (ART) result that covers up to 24 hours, or a negative PCR swab result that covers up to 72 hours, obtained from government designated testing locations or may be self- administered (site dependent requirement). There is additional documented proof of measles and diphtheria vaccination requirement for visiting Singhealth institutions.
IP Supply and delivery	 No restrictions for IP supply to sites by drug depot. DTP vendor approved by QA and may be utilised by sites if required.
General	 From 29 March 2022, there will be streamlining of COVID-19 rules as Singapore transitions to a COVID-19 resilient nation. 75% of employees who can work from home can return to the office. Border measures are further simplified to pave way for more Vaccinated Travel. 100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation.
COVID-19 Trials	 HA and EC may review COVID-19 trials on expedited basis, on a case-by-case basis. Currently there are 38 COVID-19 related trials approved in Singapore and 1 COVID vaccine trial.

Top biotech sites: High level status

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID- 19 trials
National University Hospital	Available	online (if pre-arranged)	Available	Available	On-site	-
Singapore General Hospital	Available	online (if pre-arranged)	Available	Available	On-site	-
Changi General Hospital	Available	online (if pre-arranged)	Available	Available	On-site	-
National Cancer Centre	Available	online (if pre-arranged)	Available	Available	On-site	-
Raffles Hospital	Available	online (if pre-arranged)	Available	Available	On-site	-
Tan Tock Seng Hospital	Available	online (if pre-arranged)	Available	Available	On-site	
Khoo Teck Puat Hospital	Available	online (if pre-arranged)	Available	Available	On-site	-
Curie Oncology	Available	Available (if pre-arranged)	Available	Available	On-site	-

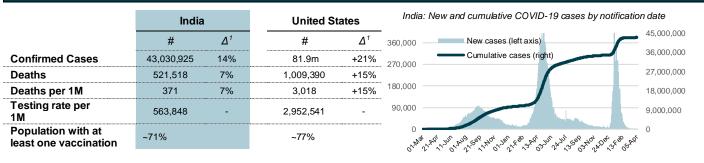
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Statista, Worldometer, Ourworldindata.org

Status as at: 5th April 2022



India COVID-19 Snapshot



⁽¹⁾ change versus previous month

India Clinical Trial Insights

Feasibility	Feasibilities are now progressing normally.
Ethics and Governance	 Most of the ethics committees are operating and reviewing clinical trials normally. Ethics committees are also advised by Indian Council of Medical Research to review COVID19 trials in expedited manner. Indian Council of Medical Research also released draft guidance to allow consenting through e-mail or text messages.
Recruitment	New patient recruitment is normal in most of the clinical study sites.
Participant visits	 The majority of top sites allow visits to occur or study participants are also provided IP to home. For study site visits for participants are using normal modes of transportation.
Monitoring	 There are no restrictions to perform onsite monitoring visits All top biotech sites allow for remote monitoring.
IP Supply and delivery	 IP supply chain is functioning and allow to deliver IP to hospitals as well as directly to participants' home. Major IP storage and distribution companies are operating normally.
General	 Presently everything is normal. There are no restrictions. Domestic travel is open and international flights with standard schedule will start operating from 28-March-2022 100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation.
COVID-19 Trials	 Regulatory submissions for all trials are conducted online as well as offline. The Ministry of Health has implemented expedited timelines for COVID trials review, but it is no longer provided in 10 days. It can take 4-8 weeks. Subject Expert Committee is meeting now on monthly basis to review COVID studies.

Top 10 sites: High level status

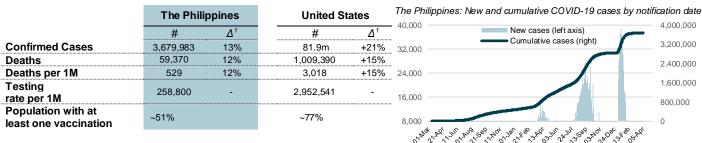
	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
King George's Medical Univ.	Available	Available	Available	Available	Onsite Monitoring	Several studies ongoing
Ruby Hall Clinical Services	Available	Available	Available	Available	Onsite Monitoring	Several studies ongoing
K.L.E.S. Dr. Prabhakar Kore Hospital	Available	Available	Available	Available	Onsite Monitoring	Several studies ongoing
King George Hospital Visakhapatnam	Available	Available	Available	Available	Onsite Monitoring	Several studies in review
Sir Ganga Ram Hospital	Available	Available	Available	Available	Onsite Monitoring	Several studies in review
Postgraduate Institute of Medical Education and Research Chandigarh	Available	Available	Available	Available	Onsite Monitoring	No studies
Curie Manavata Cancer Centre	Available	Available	Available	Available	Onsite Monitoring	1 ongoing Covid study
Deenanath Mangeshkar Hospital	Available	Available	Available	Available	Onsite Monitoring	Several studies in review
B J Medical College & Sassoon Hospital, Pune	Available	Available	Available	Available	Onsite Monitoring	Several studies in review

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

Sources: Worldometer, Ourworldindata.org



The Philippines COVID-19 Snapshot



⁽¹⁾ change versus previous month

The Philippines Clinical Trial Insights

Feasibility Majority of sites continue to be interested in new studies. Philippine FDA issued circular on Emergency Use Authorization for Covid-19 Vaccine in Dec 2020 with 21 days approval timeline. There are 8 Ethics and COVID19 vaccines given with EUA in the Philippines. FDA has priority pathway for COVID-19 treatment (30d approval) and vaccine trials (40d Governance approval). COVID-19 treatment and vaccine trial require monthly and quarterly progress status notification to FDA. Recruitment is open in most sites as community quarantine classification is down to Alert level 1 (low case transmission). However, mask is still Recruitment mandatory in public place/transportation and enclosed places and physical distancing is still required. Thus, participants require pre-arranged schedule prior to site visit to ensure there is no crowding at site. Ethics require sponsor to cover for PPE cost of subjects in clinical trial & site staff. **Participant** We are seeing several IRB requiring increases in subject travel budgets to cover for special transport arrangement going to the site. visits Onsite monitoring allowed at most sites, but caution is exercised in sites with high risk for COVID exposure for Novotech staff. Travel outside Monitorina Metro Manila (to provincial sites) may be subjected to local city travel protocol especially in locations where there is increase in reported COVID cases. Sites are open to support remote monitoring however this would be assessed on a case-by-case basis. Domestic and international flights are normal operations Inbound flights still limited but cargo flights unhampered. Domestic travellers who are fully **IP Supply** negative RT-PCR 48-hrs prior to arrival to enter the Philippines. There is no quarantine requirement for fully immunized travellers. and delivery Local logistics providers can support distribution of IP to site or direct-to-patient delivery.

- immunized against COVID-19 vaccine can travel freely without need for quarantine. Foreign inbound traveller needs to be fully immunized and with
- DTP vendor approved by QA and may be utilised by sites, if required, as a contingency

General

- Metro Manila eased to Alert #1 status from 15 March 2022 100% of Novotech staff have received their full COVID-19 vaccination, majority have received their booster shot.
- Novotech staff can work remotely but Novotech office is at 100% capacity. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation
- Government keen on COVID-19 vaccine studies involving vulnerable population e.g., paediatric and with co-morbidities. COVID-19 trials on mild indication requiring hospital admission are not feasible as these cases are sent on government isolation facilities or home quarantine. Philippines participating in WHO Solidarity Plus (treatment) and Solidarity II (vaccine) trials.

COVID-19 Trials

- COVID-19 trials will be treated as priority by Philippine FDA and the Single Joint Research Ethics Board (SJREB). COVID19 treatment trials will take 30d approval turnaround from Philippine FDA. COVID-19 vaccine trial regulatory approval takes 40d turnaround time.
- COVID-19 vaccination in adults in Metro Manila have reached more than 94%. The Philippine government aggressive with the vaccination of 12-17 years old since October2021 and began vaccination of children 5 to 11 years old in February 2022.

Darticinant

COVID 40

Top 10 sites: High level status

	Ethics/ Gov	Site Initiation	Recruitment	visits	Monitoring	trials
Davao Doctors Hospital	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available	Expedited
De La Salle Health Science Institute	Available	Available	Available	Available	Available	Expedited
Makati Medical Center	Available	Available	Available	Available	Available	Expedited
St Luke's Medical Center (SLMC) Quezon City	Available	Available	Available	Available	Available	Expedited
National Kidney & Transplant Institute (NKTI)	Available	Available	Available	Available	Available	Expedited
Philippine General Hospital	Available	Available	Available	Available	Available	Expedited
Baguio General Hospital	Available	Available	Available	Available	Available (with exceptions)	Expedited
Manila Doctors Hospital	Available	Available	Available	Available	Available	Expedited
Perpetual Succour Hospital	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available	Expedited

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

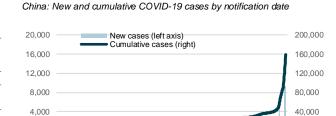
Sources: Worldometer, Ourworldindata.org

Status as at: 5th April 2022



China COVID-19 Snapshot

	China			United States			
	#	Δ^1		# Δ			
Confirmed Cases	158,793	32%		81.9m	+21%		
Deaths	4,648	-		1,009,390	+15%		
Deaths per 1M	3	-		3,018	+15%		
Testing rate pel	160,000,000	-		2,952,541	-		
Population with at least one vaccination	~88% ~77%						



(1) change versus previous month

China Clinical Trial Insights

Feasibility	Majority of sites continue to be very interested in new studies.
Ethics and Governance	Review and approval of non-COVID-19 clinical trials are continuing as scheduled.
Recruitment	Majority of sites are open for recruitment.
Participant visits	There has been limited impact for subject visits, Majority of sites are open for subject visits.
Monitoring	 45% sites restrict onsite monitoring visits. Negative PCR result or full Covid vaccination is required for on-site visit at some sites.
IP Supply and delivery	 No impact and the IP supply chain is operating with no restrictions. Negative PCR result and Certificate of disinfection and sterilization of IP is required at some sites.
General	 Sites, Industry, Health Authority and ECs coordinating activities to ensure subject safety and trial continuity. 100% of Novotech staff can work remotely with office access if required.
COVID-19 Trials	 Very Low levels of investigator interest, institutional support, and acceleration of processes from ethics/regulatory authorities for COVID-19 trials.

Top 10 sites: High level status

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
The Affiliated Hospital, Of Xuzhou Medical, University	Available	Available	Available	Available	Not available onsite or remote	Not expedited
Henan Cancer Hospital	Available	Available	Available	Available	Available onsite	Not expedited
Harbin Medical University Cancer Hospital	Available	Not available	Available	Available	Not available onsite or remote	Not expedited
Jiangsu Province Hospital	Available	Available (remote)	Available	Available	Available onsite	Not expedited
Beijing Cancer Hospital	Available	Available (remote)	Available	Available	Remote visits	Not expedited
The First Affiliated Hospital of Zhengzhou University	Available	Available	Available	Available	Available onsite	Not expedited
Xuzhou Central Hospital	Available	Not available	Available	Available	Not available onsite or remote	Not expedited
Hunan Cancer Hospital	Available	Available	Available	Available	Available onsite and remote	Not expedited
Cancer Hospital of The University of Chinese Academy of sciences	Available	Available	Available	Available	Available onsite	Not expedited
The First Affiliated Hospital	Available	Available (remote)	Not available	Available	Available onsite	Not expedited

Note: For the sites allows for on-site monitoring, there is specific requirement for the monitors according to the local policy, including but not limited: Local CRA, PCR testing results negative within 48 hours, Green Healthy Bar-Code, No Star Remarks of the CRA's travel history records etc.

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Sources: Worldometer, Ourworldindata.org

Status as at: 5th April 2022

