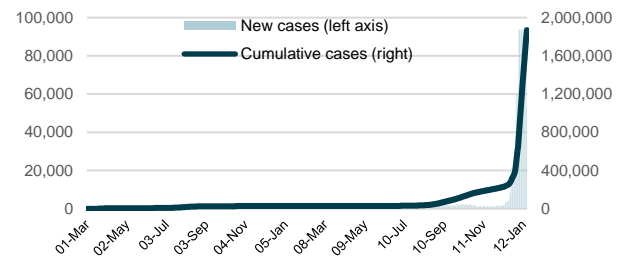


Australia COVID-19 Snapshot

	Australia		United States	
	#	Δ^1	#	Δ^1
Confirmed Cases	1,869,728	954%	67.6m	+43%
Deaths	2,776	55%	874,321	+13%
Deaths per 1M	107	55%	2,618	+13%
Testing rate per 1M	2,277,692	-	2,582,225	-
Population with at least one vaccination	~81%		~75%	

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



(1) change versus previous month

Australia Clinical Trial Insights

Feasibility	<ul style="list-style-type: none"> Majority of sites continue to be very interested in new studies.
Ethics and Governance	<ul style="list-style-type: none"> Review and approval of clinical trials are continuing as scheduled. All submissions completed electronically, and legal documents e-signed.
Recruitment	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Passenger jet volume increasing to 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	<ul style="list-style-type: none"> Flights within Australia are increasing, and we are able to travel across state borders with the exception of Western Australia. There are currently no lockdowns however there are some restrictions in line with social distancing measures. Australian Health Authority has approved the Pfizer, AstraZeneca and Moderna vaccines for deployment as per phased Vaccination Rollout Plan which now includes children from 5 – 11 years old. The Australian adult population is almost 80% double vaccinated. CRA's were offered support to present for vaccination under Phase 1b as per healthcare worker status. 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 Trials	<ul style="list-style-type: none"> High levels of investigator interest, institutional support, and acceleration of processes from ethics/regulatory authorities 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	Remote visits	Expedited
Nucleus Network Ltd	Available	Available	Available	Available	Available onsite (exceptions)	Only vaccine trials expedited
Royal Adelaide Hospital	Available	Available (remote)	Not recruiting currently	Available	Not available onsite or remote	Expedited
The Alfred Hospital	Available	Available	Available (except for respiratory)	Available (except for respiratory)	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 (except for Gastro)	Remote visits	Remote visits	Expedited

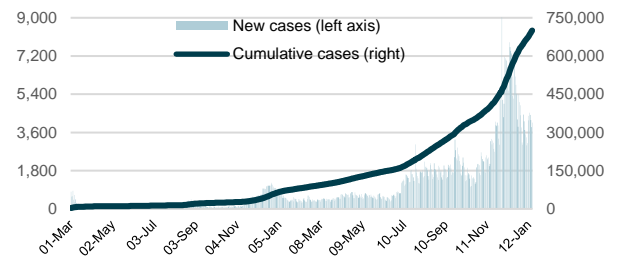
Novotech monitors activity for all sites. Please contact your project manager for an update

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

South Korea COVID-19 Snapshot

	South Korea		United States	
	#	Δ^1	#	Δ^1
Confirmed Cases	700,102	+86%	67.6m	+43%
Deaths	6,378	+117%	874,321	+13%
Deaths per 1M	124	+118%	2,618	+13%
Testing rate per 1M	307,848	-	2,582,225	-
Population with at least one vaccination	~87%		~75%	

South Korea: New and cumulative COVID-19 cases by notification date



(1) change versus previous month

South Korea Clinical Trial Insights

Feasibility	<ul style="list-style-type: none"> Majority of sites continue to be very interested in new studies.
Ethics and Governance	<ul style="list-style-type: none"> Review and approval of non-COVID-19 clinical trials are continuing as scheduled.
Recruitment	<ul style="list-style-type: none"> Clinical trial sites are open, and recruitment is ongoing at all trial sites.
Participant visits	<ul style="list-style-type: none"> Subject visits are available at all sites with social distancing measures implemented.
Monitoring	<ul style="list-style-type: none"> Monitoring visits are limited in a few top sites, very competitive monitoring room booking found with limited capacity.
IP Supply and delivery	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 63 COVID-19 trials approved in South Korea. Novotech is involved on two of these projects. 7 Covid-19 new drug approval by MFDS: 5 vaccines (2 AstraZeneca, Pfizer, Janssen, Moderna), 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

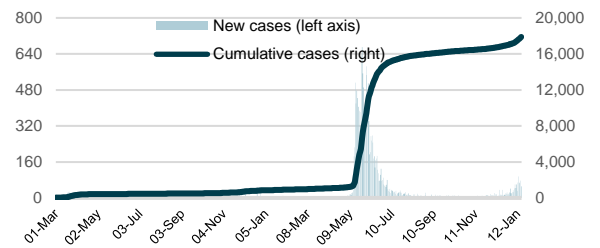
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.org

Taiwan COVID-19 Snapshot

	Taiwan		United States	
	#	Δ^1	#	Δ^1
Confirmed Cases	17,885	9%	67.6m	+43%
Deaths	851	-	874,321	+13%
Deaths per 1M	36	3%	2,618	+13%
Testing rate per 1M	410,435	-	2,582,225	-
Population with at least one vaccination	~79%		~75%	

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



(1) change versus previous month

Taiwan Clinical Trial Insights

Feasibility	<ul style="list-style-type: none"> Majority of sites continue to be very interested in new studies.
Ethics and Governance	<ul style="list-style-type: none"> Review and approval of clinical trials are continuing as scheduled.
Recruitment	<ul style="list-style-type: none"> Sites are open for recruitment.
Participant visits	<ul style="list-style-type: none"> Sites are open for subject visits at all sites.
Monitoring	<ul style="list-style-type: none"> Negative PCR and rapid test can be waived if fully vaccinated, applicable for on-site monitoring at most of sites. Very competitive monitoring room booking found with limited capacity at some sites
IP Supply and delivery	<ul style="list-style-type: none"> No impact and the IP supply chain is operating with no restrictions.
General	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> High levels of 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
National Taiwan University	Available	Available	Available	Available	Available (PCR test/Rapid test within 3 days)	Expedited
China Medical University	Available	Available	Available	Available	Available	Expedited
Chang Gung Memorial Hospital- Linko	Available	Available	Available	Available	Available (PCR test within 3 days)	Expedited
Taipei Veterans General	Available	Available	Available	Available	Available	Expedited
Chang Gung Memorial Hospital Kaohsiung	Available	Available	Available	Available	Available (PCR test within 3 days)	Expedited
Kaohsiung Medical University Hospital	Available	Available	Available	Available	Available (PCR test within 3 days)	Expedited
Tri-service General Hospital	Available	Available	Available	Available	Available (PCR test/ Rapid test within 3 days)	Expedited
Chung Shan Medical University Hospital	Available	Available	Available	Available	Available	Expedited
Changhua Christian Hospital	Available	Available	Available	Available	Available (PCR/ Rapid test within 3 days)	Expedited
Chi Mei Medical Center	Available	Available	Available	Available	Available (PCR within 7 days / Rapid test within 3 days)	Expedited
Taichung Veterans General	Available	Available	Available	Available	Available	Expedited

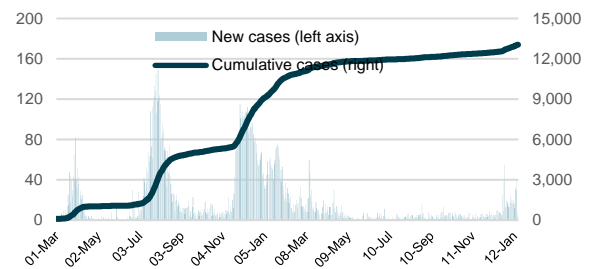
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.org

Hong Kong COVID-19 Snapshot

	Hong Kong		United States	
	#	Δ^1	#	Δ^1
Confirmed Cases	13,048	6%	67.6m	+43%
Deaths	213	-	874,321	+13%
Deaths per 1M	28	-	2,618	+13%
Testing rate per 1M	4,128,836	-	2,582,225	-
Population with at least one vaccination	~68%		~75%	

Hong Kong: New and cumulative COVID-19 cases by notification date



(1) change versus previous month

Hong Kong Clinical Trial Insights

Feasibility	<ul style="list-style-type: none"> Majority of sites continue to be very interested in new studies.
Ethics and Governance	<ul style="list-style-type: none"> Review and approval of non-COVID-19 clinical trials are continuing as scheduled.
Recruitment	<ul style="list-style-type: none"> All top 10 sites are open for recruitment.
Participant visits	<ul style="list-style-type: none"> In public sites, subject visits are 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	<ul style="list-style-type: none"> Some public sites restrict onsite monitoring visits. Private sites remain opened. Negative PCR 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	<ul style="list-style-type: none"> No impact and the IP supply chain is operating with no restrictions.
General	<ul style="list-style-type: none"> 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. DoH approved Pfizer and Sinovac vaccines.
COVID-19 Trials	<ul style="list-style-type: none"> High levels of investigator interest, institutional support, and acceleration of processes from ethics/regulatory authorities for COVID-19 trials.

Top biotech sites: High level status

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

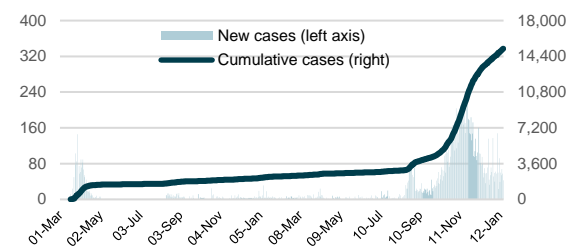
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.or

New Zealand COVID-19 Snapshot

	New Zealand		United States	
	#	Δ ¹	#	Δ ¹
Confirmed Cases	15,170	113%	67.6m	+43%
Deaths	52	79%	874,321	+13%
Deaths per 1M	10	67%	2,618	+13%
Testing rate per 1M	1,161,541	-	2,582,225	-
Population with at least one vaccination	~78%		~75%	

New Zealand: New and cumulative COVID-19 cases by notificatio date



(1) change versus previous month

New Zealand Clinical Trial Insights

Feasibility	<ul style="list-style-type: none"> Sites continue to be very interested in new studies.
Ethics and Governance	<ul style="list-style-type: none"> Review and approval of non-COVID-19 clinical trials are continuing as previously scheduled for majority of sites. Some delays have been observed because of an influx of trials into New Zealand.
Recruitment	<ul style="list-style-type: none"> Sites continue to recruit patients across the country.
Participant visits	<ul style="list-style-type: none"> Patient visits are ongoing.
Monitoring	<ul style="list-style-type: none"> On-site monitoring visits have resumed across New Zealand as we are now in the Traffic Light system and the majority of the country is in the Orange Light.
IP Supply and delivery	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> New Zealand is under the Orange Light with exception of Northland. Travel to Northland will require business travel exemption documents. At the Orange Light on-site monitoring visits can occur. A travel bubble involving isolation free travel between Australia and New Zealand is on-hold. The travel bubble between the Cook Island and New Zealand on hold. 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 and AstraZeneca Covid-19 vaccines.
COVID-19 Trials	<ul style="list-style-type: none"> 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.or

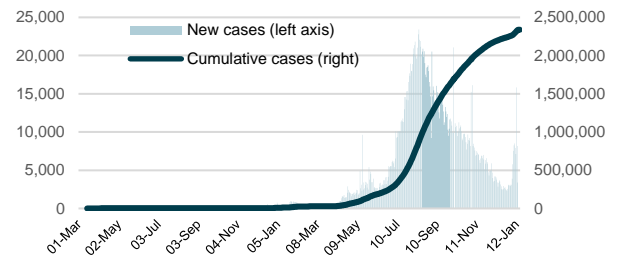
Thailand COVID-19 Snapshot

COVID-19 Client Bulletin

Status as at: 19 January 2022

	Thailand		United States	
	#	Δ ¹	#	Δ ¹
Confirmed Cases	2,337,811	20%	67.6m	+43%
Deaths	21,959	12%	874,321	+13%
Deaths per 1M	313	12%	2,618	+13%
Testing rate per 1M	246,478	-	2,582,225	-
Population with at least one vaccination	~79%		~75%	

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



(1) change versus previous month

Thailand Clinical Trial Insights

- Feasibility**
 - Sites continue to be very interested in new studies.
- Ethics and Governance**
 - 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
 - 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

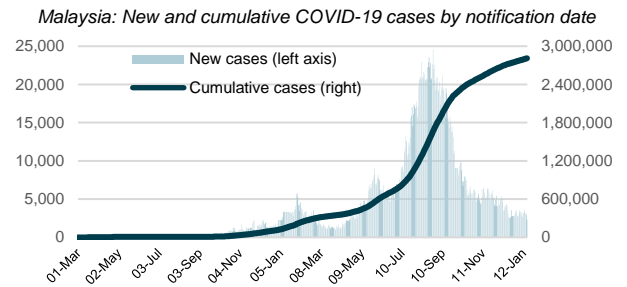
	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
Maharaj Nakorn Chiang Mai Hospital	Available	Available	Available	Available	Available	Expedited
Srinagarind Hospital	Available	Available	Available	Available	Available	Expedited
Siriraj Hospital	Available	Available	Available	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

	Malaysia		United States	
	#	Δ^1	#	Δ^1
Confirmed Cases	2,810,689	13%	67.6m	+43%
Deaths	31,808	9%	874,321	+13%
Deaths per 1M	964	9%	2,618	+13%
Testing rate per 1M	1,304,041	-	2,582,225	-
Population with at least one vaccination	-79%		-75%	



(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.
- General**
 - The Malaysian government has relaxed restrictions on most states and businesses.
 - Interstate and Inter-district travel now permitted for fully vaccinated individuals.
 - 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

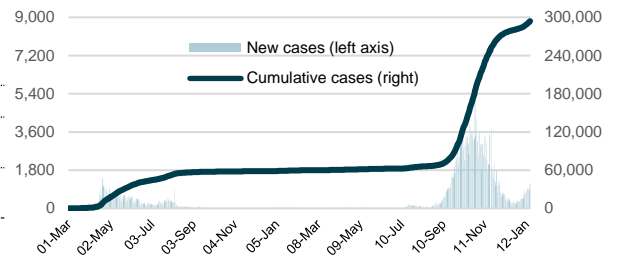
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.or

Singapore COVID-19 Snapshot

	Singapore		United States	
	#	Δ^1	#	Δ^1
Confirmed Cases	294,014	39%	67.6m	+43%
Deaths	843	84%	874,321	+13%
Deaths per 1M	142	82%	2,618	+13%
Testing rate per 1M	3,563,173	-	2,582,225	-
Population with at least one vaccination	~88%		~75%	

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



(1) change versus previous month

Singapore 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 PCR swab result within 72 hours from government designated testing locations.
- 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**
 - Currently work from home is default for Singapore office. 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	Onsite (Expedited
Singapore General Hospital	Available	online (if pre-arranged)	Available	Available	Onsite (Expedited
Changi General Hospital	Available	online (if pre-arranged)	Available	Available	Onsite	Expedited
National Cancer Centre	Available	online (if pre-arranged)	Available	Available	Onsite	-
Raffles Hospital	Available	online (if pre-arranged)	Available	Available	Onsite	-
Tan Tock Seng Hospital	Available	online (if pre-arranged)	Available	Available	Onsite	Expedited
Khoo Teck Puat Hospital	Available	online (if pre-arranged)	Available	Available	On-site	Expedited
Curie Oncology	Available	Available (if pre-arranged)	Available	Available	Onsite	-

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

Sources: Statista, Worldometer, Ourworldindata.org

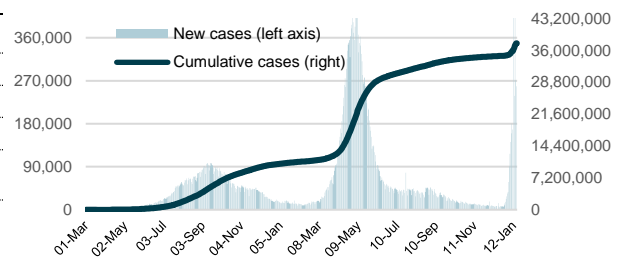
India COVID-19 Snapshot

COVID-19 Client Bulletin

Status as at: 19 January 2022

	India		United States	
	#	Δ ¹	#	Δ ¹
Confirmed Cases	37,618,271	10%	67.6m	+43%
Deaths	486,784	6%	874,321	+13%
Deaths per 1M	347	5%	2,618	+13%
Testing rate per 1M	503,527	-	2,582,225	-
Population with at least one vaccination	~65%		~75%	

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



(1) change versus previous month

India Clinical Trial Insights

Feasibility	<ul style="list-style-type: none"> Feasibilities are now progressing normally.
Ethics and Governance	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> New patient recruitment is normal in most of the clinical study sites.
Participant visits	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Onsite monitoring visits are possible but depending upon approval from the site. We are now able to perform onsite monitoring visits. All top biotech sites allow for remote monitoring.
IP Supply and delivery	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Local government bodies are imposing lockdowns in specific cities or states. There is no pan India lockdown. During this time all medical / healthcare facilities remain open with a focus on COVID-19 management. 100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation. Regulatory submissions for all trials are conducted online.
COVID-19 Trials	<ul style="list-style-type: none"> The Ministry of Health has implemented expedited timelines for COVID trials review (within 10 working days). Subject Expert Committee is meeting every week to review COVID studies.

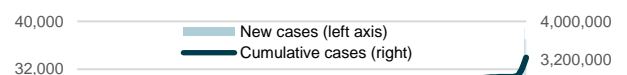
Top 10 sites: High level status

	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



	The Philippines		United States		The Philippines: New and cumulative COVID-19 cases by notification date
	#	Δ ¹	#	Δ ¹	
Confirmed Cases	3,242,374	16%	67.6m	+43%	
Deaths	52,929	21%	874,321	+13%	
Deaths per 1M	473	20%	2,618	+13%	
Testing rate per 1M	235,508	-	2,582,225	-	
Population with at least one vaccination	~55%		~75%		

(1) change versus previous month

The Philippines Clinical Trial Insights

Feasibility	<ul style="list-style-type: none"> Majority of sites continue to be interested in new studies however some delays in response are expected as some investigators are frontliners.
Ethics and Governance	<ul style="list-style-type: none"> Philippine FDA issued circular on Emergency Use Authorization for Covid-19 Vaccine in Dec 2020 with 21 days approval timeline. There are 8 COVID19 vaccines given with EUA in the Philippines. FDA has priority pathway for COVID-19 treatment (30d approval) and vaccine trials (40d approval). COVID-19 treatment and vaccine trial require monthly and quarterly progress status notification to FDA.
Recruitment	<ul style="list-style-type: none"> Movement restriction eases in Metro Manila with Alert 3 status. Recruitment in studies targeting <18yo or >60yo population may require special arrangement due to general restrictions for this age group to stay at home and only allowed to go out for access essential goods/services. Sites have resumed clinical trial activities, however, increase in COVID cases admission in hospital may delay the site's ability to deliver study activities. COVID-19 recruitment of studies requiring hospital admission of mild COVID-19 severity is affected by the shift of patient management and are generally not admitted in the hospital instead are housed in government isolation facility to give priority to severe to critical COVID-19 cases for hospital admission. Ethics require sponsor to cover for PPE cost of subjects in clinical trial & site staff.
Participant visits	<ul style="list-style-type: none"> We are seeing several IRB requiring increases in subject travel budgets to cover for special transport arrangement going to the site.
Monitoring	<ul style="list-style-type: none"> Onsite monitoring allowed at most sites, but caution is exercised in sites with high risk for COVID exposure of Novotech staff. Travel outside Metro Manila (to provincial sites) may be subjected to local city travel restrictions especially in locations where there is increase in reported COVID cases. Metro Manila curfew hours implemented again from 12MN to 4am. Sites are open to support remote monitoring however this would be assessed on a case-by-case basis.
IP Supply and delivery	<ul style="list-style-type: none"> Domestic flights have resumed with reduced flight schedule and movement may be subjected to different quarantine restrictions that may cause delay. Inbound flights still limited but cargo flights unhampered. Local logistics providers can support distribution of IP to site or direct-to-patient delivery. DTP vendor approved by QA and may be utilised by sites, if required, as a contingency
General	<ul style="list-style-type: none"> Metro Manila eased to Alert #3 status until 15 November 2021 (work related travel is allowed subject to compliance to border requirements including negative RT-PCR test and vaccination). 100% of Novotech staff have received their full COVID-19 vaccination. Novotech staff can work remotely but Novotech office is at 100% capacity. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation
COVID-19 Trials	<ul style="list-style-type: none"> Strong interest in Covid-19 trials for on post-COVID-19 indication. Government keen on COVID-19 vaccine studies involving vulnerable population e.g., paediatric and with co-morbidities. Metro Manila hospitals now easing on occupancy however admissions still give priority for moderate-severe COVID cases. COVID-19 trials on mild indication requiring hospital admission is not feasible as these cases are recommended in government isolation facilities or home quarantine. Philippines participating in WHO Solidarity Plus (treatment) and Solidarity II (vaccine) 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 will require additional clearance by the Vaccine Expert Panel with regulatory approval at 40d turnaround time. COVID-19 vaccination in adults in Metro Manila have reached 80%. The Philippine government targeting to achieve >90% of population in Metro Manila vaccinated by year end and vaccination of 12-17 years old have started in October2021.

Top 10 sites: High level status

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 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