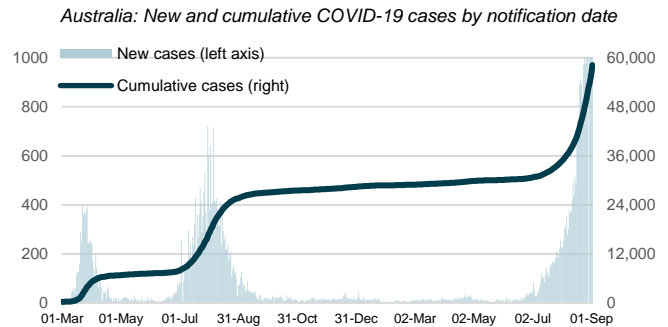


Australia COVID-19 Snapshot

	Australia		United States	
	#	Δ ¹	#	Δ ¹
Confirmed Cases	58,206	73%	40,513,018	+14%
Deaths	1,032	12%	662,853	+6%
Deaths per 1M	40	11%	1,989	+5%
Testing rate per 1M	1,246,945	-	1,766,004	-
Population with at least one vaccination	49%		62%	

(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"> All the top 10 sites are open for recruitment and for SIVs for new studies.
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"> Most sites are now open to onsite or remote monitoring visits. 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"> Greater Sydney remains in a lockdown until the end of August with essential services only remaining open. Australian Health Authority has approved the Pfizer and AstraZeneca vaccines for deployment as per phased Vaccination Rollout Plan. CRAs are being 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 (exceptions)	Available (except oncology)	Available	Remote visits (exceptions)	Expedited
Monash Hospital	Available	Available (remote)	Available (exceptions)	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	Available	Available	Available onsite	Expedited
The Alfred Hospital	Available	Available	Available (except for respiratory)	Available (except for respiratory)	Remote visits	Expedited
Austin Hospital	Available	Available (remote)	Available	Available	Remote visits	Requires exec approval
Royal Prince Alfred Hospital	Available	Available	Available	Available	Available (exceptions)	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	On Hold

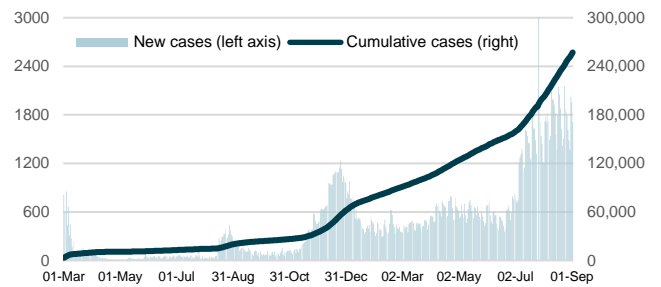
Novotech monitors activity for all sites. Please contact your project manager for an update

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

South Korea COVID-19 Snapshot

	South Korea		United States	
	#	Δ ¹	#	Δ ¹
Confirmed Cases	257,110	+32%	40,513,018	+14%
Deaths	2308	+11%	662,853	+6%
Deaths per 1M	45	+10%	1,989	+5%
Testing rate per 1M	258,895	-	1,766,004	-
Population with at least one vaccination	~58%		~62%	

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 some 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. Electronic signature accepted.
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.
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 60 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

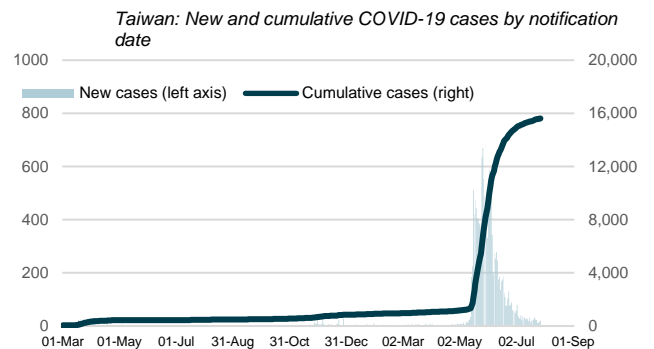
	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
Asan Medical Center	Available	On site or Remote	Available	Available	Available	Expedited
Samsung Medical Center	Available	On site or Remote	Available	Available	Available (limited seats)	Expedited
Seoul National University 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	On hold	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	16,012	+3%	40,513,018	+14%
Deaths	837	+6%	662,853	+6%
Deaths per 1M	35	+6%	1,989	+5%
Testing rate per 1M	215,308	-	1,766,004	-
Population with at least one vaccination	~42%		~62%	



(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 site.
- Monitoring**
 - Negative PCR result or rapid test is required for on-site monitoring at most of sites.
 - Very competitive monitoring room booking found with limited capacity.
- IP Supply and delivery**
 - No impact and the IP supply chain is operating with no restrictions.
- General**
 - 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 vaccine 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 (Rapid test)	Expedited
China Medical University	Available	Remote	Available	Available	Available	Expedited
Chang Gung Memorial Hospital- Linko	Available	Available	Available	Available	Available (PCR test)	Expedited
Taipei Veterans General	Available	Remote	Available	Available	Available	Expedited
Chang Gung Memorial Hospital Kaohsiung	Available	Available	Available	Available	Available (PCR test)	Expedited
Kaohsiung Medical University Hospital	Available	Available	Available	Available	Available (PCR test)	Expedited
Tri-service General Hospital	Available	Available	Available	Available	Available (PCR test)	Expedited
Chung Shan Medical University Hospital	Available	Available	Available	Available	Available	Expedited
Changhua Christian Hospital	Available	Available	Available	Available	Available	Expedited
Chi Mei Medical Center	Available	Available	Available	Available	Available (PCR/ Rapid test)	Expedited
Taichung Veterans General	Available	Available	Available	Available	Available	Expedited

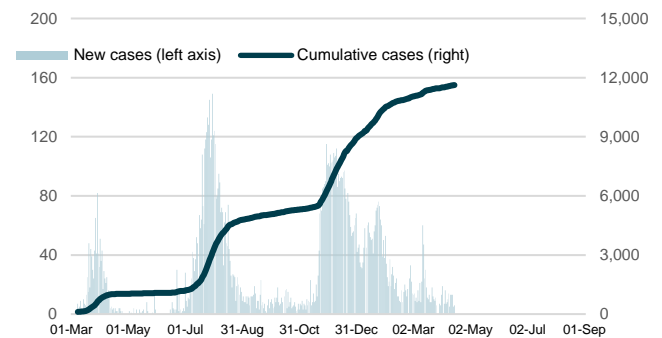
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.org

Hong Kong COVID-19 Snapshot

	Hong Kong		United States	
	#	Δ^1	#	Δ^1
Confirmed Cases	12,114	+1 %	40,513,018	+14%
Deaths	212	+0 %	662,853	+6%
Deaths per 1M	28	0%	1,989	+5%
Testing rate per 1M	3,114,489	-	1,766,004	-
Population with at least one vaccination	~55%		~62%	

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"> All sites (public and private) are open for onsite monitoring visits.
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	Available	Available	Available onsite	Expedited
Princess Margaret Hospital	Available	Available	Available	Available	Available onsite	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	Available	Available	Available onsite	Expedited
Humanity & Health Research Center	Available	Available	Available	Available	Available onsite	-
Pamela Youde Nethersole Eastern Hospital	Available	Available	Available	Available	Available onsite	Expedited
Hong Kong United Oncology	Available	Available	Available	Available	Available onsite	-
UNIMED Medical Institute	Available	Available	Available	Available	Available onsite	-

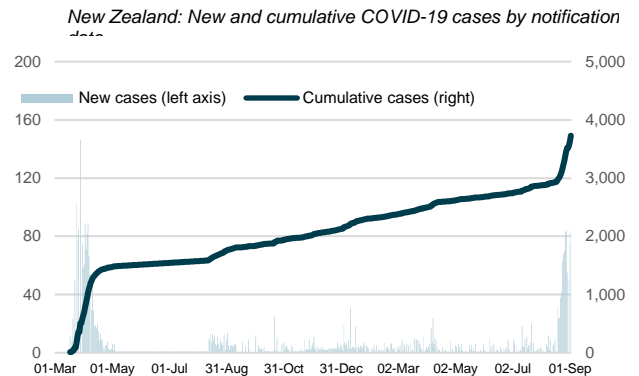
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.or

New Zealand COVID-19 Snapshot

	New Zealand		United States	
	#	Δ ¹	#	Δ ¹
Confirmed Cases	3,729	+30%	40,513,018	+14%
Deaths	26	0%	662,853	+6%
Deaths per 1M	5	0%	1,989	+5%
Testing rate per 1M	604,600	-	1,766,004	-
Population with at least one vaccination	~50%		~62%	

(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 as a result 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; however limited due to the current Alert Level 4, site recruitment is also impacted due to the current alert level. Healthy volunteers are recruiting to studies under critical pathways.
Monitoring	<ul style="list-style-type: none"> On-site monitoring visits are currently on hold across New Zealand.
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 has implemented Alert Level 4 for Auckland until the 22nd September. At level 4 sites visits will only occur remotely. All regions outside of Auckland has moved to Alert Level 3. At level 3 sites visits will only occur remotely however some sites will increase business activities. Regional travel including flying is not permitted across the country. Controls at the borders remain for those entering New Zealand, including health screening, testing for all arrivals, and mandatory 14-day managed quarantine or isolation. 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 Covid-19 vaccine.
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 (Remote)	Available (Critical Studies)	Available (Critical Studies)	Available (Remote)	Expedited
Auckland City Hospital	Available	On Hold	On Hold	On Hold	Available (remote)	Expedited
Christchurch Hospital	Available	On Hold	On Hold	On Hold	Available	Expedited
Middlemore Hospital	Available	On Hold	On Hold	On Hold	Available (remote)	Expedited
NZCR (Christchurch Clinical Studies Trust)	Available	Available (Remote)	Available (Critical Studies)	Available (Critical Studies)	Available (Remote)	Expedited
Clinical Trials New Zealand	Available	On Hold	Available	Available	Available (Remote)	Expedited
Dunedin Hospital	Available	On Hold	On Hold	On Hold	On Hold	Expedited
Christchurch Diabetes Centre	Available	On Hold	On Hold	On Hold	On Hold	Expedited
New Zealand Brain Research Institute	Available	On Hold	On Hold	On Hold	On Hold	Expedited

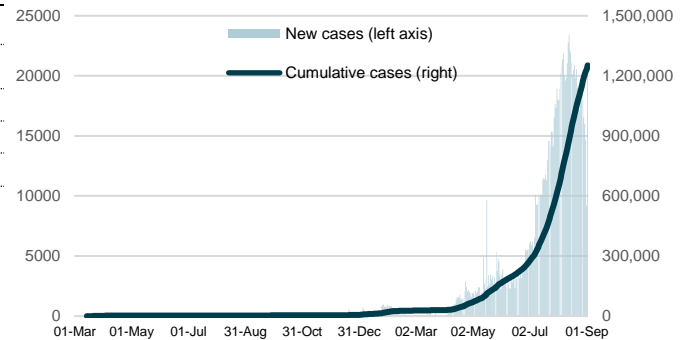
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.or

Thailand COVID-19 Snapshot

	Thailand		United States	
	#	Δ^1	#	Δ^1
Confirmed Cases	1,252,156	+123%	40,513,018	+14%
Deaths	12,374	+171%	662,853	+6%
Deaths per 1M	177	+181%	1,989	+5%
Testing rate per 1M	116,130	-	1,766,004	-
Population with at least one vaccination	~35%		~62%	

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



(1) change versus previous month

Thailand 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"> Ethics Committees are accepting new projects online or via a portal as normal .
Recruitment	<ul style="list-style-type: none"> Recruitment is open.
Participant visits	<ul style="list-style-type: none"> Participant visit is resumed to normal.
Monitoring	<ul style="list-style-type: none"> Onsite monitoring visits are restricted during lockdown, 12 Jul – 15 Sep 2021.
IP Supply and delivery	<ul style="list-style-type: none"> Except for cargo flights, Thailand is closed for international flights until further notice. This may impact on IP study supplies and lab sample shipments coming in and out of Thailand. Domestic flights are not operated during lockdown. Marken vendor approved by QA and may be utilised by sites, if required, as a contingency.
General	<ul style="list-style-type: none"> Novotech office in Bangkok is closed and 100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation. Public COVID-19 vaccine rollout is from June'21 onward and 33% of total population receiving at least first dose.
COVID-19 Trials	<ul style="list-style-type: none"> 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	By video	Available	Available	By video	Expedited
Srinagarind Hospital	Available	By video	Available	Available	By video	Expedited
Siriraj Hospital	Available	By video	Available	Available	By video	Expedited
Songklanagarind Hospital	Available	By video	Available	Available	By video	Expedited
King Chulalongkorn Memorial Hospital	Available	By video	Available	Available	By video	Expedited
Phramongkutklao Hospital	Available	By video	Available	Available	By video	Expedited
Thammasat Hospital	Available	By video	On-hold	Available	By video	Expedited
Ramathibodi Hospital	Available	By video	Available	Available	By video	Expedited
Rajavithi Hospital	Available	By video	Available	Available	By video	Expedited

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

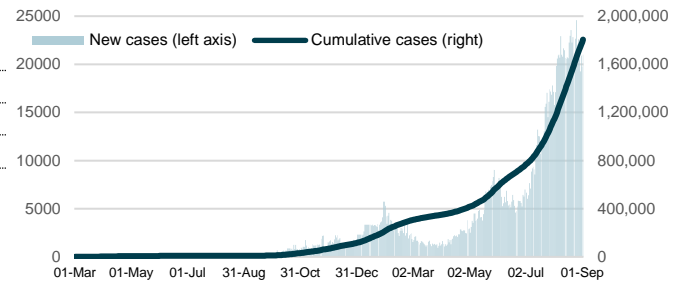
Sources: Worldometer, Ourworldindata.org

Malaysia COVID-19 Snapshot

	Malaysia		United States	
	#	Δ ¹	#	Δ ¹
Confirmed Cases	1,805,382	+70%	40,513,018	+14%
Deaths	17,521	+105%	662,853	+6%
Deaths per 1M	533	+104%	1,989	+5%
Testing rate per 1M	705,080	-	1,766,004	-
Population with at least one vaccination	-61%		-62%	

(1) change versus previous month

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



Malaysia Clinical Trial Insights

Feasibility	<ul style="list-style-type: none"> Majority of sites continue to be very interested in new studies however some delays in response are expected.
Ethics and Governance	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Recruitment is ongoing at sites, subject to Principal Investigator's discretion/ Hospital's direction, however this may be impacted by the travel restrictions imposed by the government.
Participant visits	<ul style="list-style-type: none"> Most sites remain open for subject visits, subject to Principal Investigator's discretion/ Hospital's direction.
Monitoring	<ul style="list-style-type: none"> Onsite monitoring visits are currently prohibited, due to nationwide lockdown restrictions. Remote monitoring is allowed at most sites, with remote SDV limited at certain sites.
IP Supply and delivery	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> The Malaysian government has increased restrictions on certain states and businesses. No interstate and inter-district travel is allowed currently. 100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation.
COVID-19 Trials	<ul style="list-style-type: none"> 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 (remotely)	Available	Available	On site (with conditions)	Expedited
Hospital Kuala Lumpur	Available	Available (remotely)	Available	Available	Remote	Expedited
Hospital Pulau Pinang	Available	Available (remotely)	Available	Available	Remote	Expedited
Hospital Ampang	Available	Available (remotely)	Available	Available	Remote	Expedited
Hospital Umum Sarawak	Available	Available (remotely)	Available	Available	Remote	Expedited
Hospital Raja Perempuan Zainab II	Available	Available (remotely)	Available	Available	Remote	Expedited
Hospital Raja Permaisuri Bainun	Available	Available (remotely)	Available	Available	Remote	Expedited
Hospital Serdang	Available	Available (remotely)	Available	Available	Remote	Expedited
Hospital Sultan Ismail	Available	Available (remotely)	Available	Available	Remote	Expedited
Hospital Tengku Ampuan Afzan	Available	Available (remotely)	Available	Available	Remote	Expedited

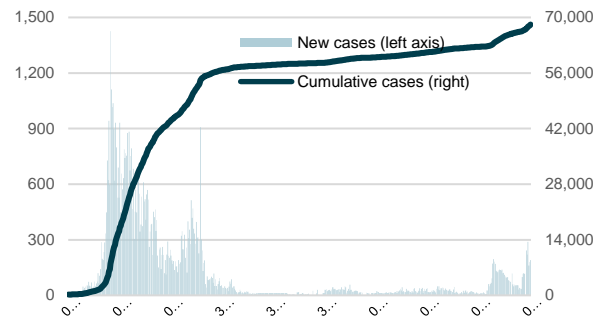
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.or

Singapore COVID-19 Snapshot

	Singapore		United States	
	#	Δ^1	#	Δ^1
Confirmed Cases	68,210	6%	40,513,018	+14%
Deaths	55	49%	662,853	+6%
Deaths per 1M	9	50%	1,989	+5%
Testing rate per 1M	3,010,260	-	1,766,004	-
Population with at least one vaccination	~78%		~62%	

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 on hold for most of the 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**
 - For most of the sites onsite monitoring visits only allowed to life saving studies.
- 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**
 - Office is open at 50% capacity 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-hold (Depending on the study)	Expedited
Singapore General Hospital	Available	online (if pre-arranged)	Available	Available	On-hold (Depending on the study)	Expedited
Changi General Hospital	Available	online (if pre-arranged)	On-hold	Available	On-hold	Expedited
National Cancer Centre	Available	online (if pre-arranged)	Available	Available	On-hold	-
Raffles Hospital	Available	online (if pre-arranged)	Available	Available	On-hold	-
Tan Tock Seng Hospital	Available	online (if pre-arranged)	Available	Available	On-hold	Expedited
Khoo Teck Puat Hospital	Available	online (if pre-arranged)	On-hold	Available	On-hold	Expedited
Curie Oncology	Available	Available (if pre-arranged)	Available	Available	Onsite (with pre-arrangement)	-

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

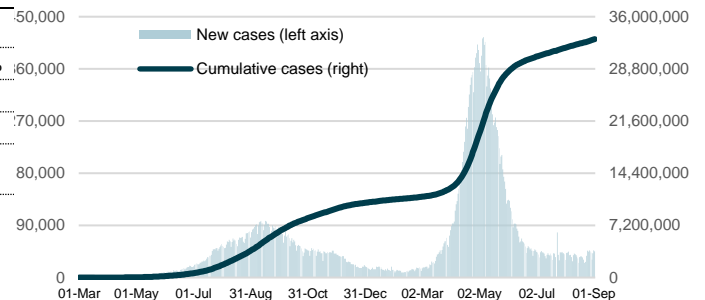
Sources: Statista, Worldometer, Ourworldindata.org

India COVID-19 Snapshot

	India		United States	
	#	Δ ¹	#	Δ ¹
Confirmed Cases	32,903,289	+4%	40,513,018	+14%
Deaths	439,916	+4%	662,853	+6%
Deaths per 1M	315	+4%	1,989	+5%
Testing rate per 1M	377,211	-	1,766,004	-
Population with at least one vaccination	~37%		~62%	

(1) change versus previous month

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



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.
COVID-19 Trials	<ul style="list-style-type: none"> Regulatory submissions for all trials are conducted online. 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

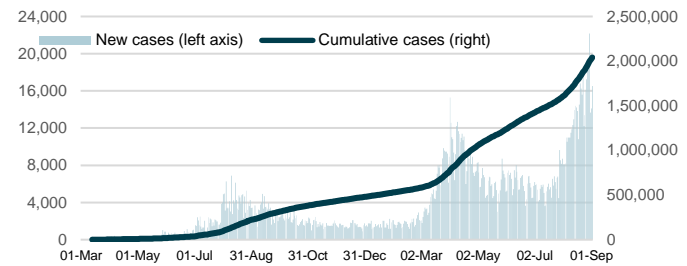
Novotech monitors activity for all sites. Please contact your project manager for an update

Sources: Worldometer, Ourworldindata.org

The Philippines COVID-19 Snapshot

	The Philippines		United States	
	#	Δ ¹	#	Δ ¹
Confirmed Cases	2,040,568	+30%	40,513,018	+14%
Deaths	33,873	+24%	662,853	+6%
Deaths per 1M	304	+23%	1,989	+5%
Testing rate per 1M	169,607	-	1,766,004	-
Population with at least one vaccination	~13%		~62%	

The Philippines: New and cumulative COVID-19 cases by notification date



(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 7 COVID19 vaccines given with EUA. FDA has priority pathway for COVID-19 treatment (30d approval) and vaccine trials (40d approval).
Recruitment	<ul style="list-style-type: none"> Recruitment in studies is open but there is slow down due to limited movement imposed by current Alert 3 (MECQ) status in Metro Manila and few provinces. Recruitment in studies targeting <18yo or >60yo population may require special arrangement due to general restrictions for this age group to be on home quarantine. Sites have resumed clinical trial activities, however, increase in COVID cases admission in hospital in August 2021 may delay the site's ability to deliver study activities. COVID-19 recruitment of studies in mild severity is affected by the shift of patient management and these patients 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 increase of 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 of COVID exposure for 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 10pm to 4am until end July. 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 be 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"> Alert 3 or Modified Enhanced Community Quarantine (MECQ) status implemented in Metro Manila and other provinces until 7 September 2021 (work related travel is allowed subject to compliance to border requirements including negative RT-PCR test and travel pass approval). >85% of Novotech staff have received their full COVID-19 vaccination. 100% of Novotech staff can work remotely but Novotech office is open with 50% capacity. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation Strong interest in Covid-19 trials for severe or post-acute infection and COVID-19 vaccine studies. Metro Manila hospitals capacity stretched and admissions priority for moderate-severe COVID admissions, recruitment for mild to moderate indications is affected. Philippines participating in WHO Solidarity Plus (treatment) and Solidarity II (vaccine) trials.
COVID-19 Trials	<ul style="list-style-type: none"> 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 layer of approval by the Vaccine Expert Panel with regulatory approval at 40d turnaround time. Several investigators indicated interest in Covid-19 MAb treatment trial and Covid-19 vaccine trial.

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)	On-hold due to surge	Expedited
De La Salle Health Science Institute	Available	Available	Available	Available	On-hold due to surge	Expedited
Makati Medical Center	Available	Available	Available	Available	Available	Expedited
St Luke's Medical Center (SLMC)	Available	Available	Available	Available	Available	Expedited
Quezon City 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	On-hold due to surge	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)	On-hold due to surge	Expedited

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

Sources: Worldometer, Ourworldindata.org