

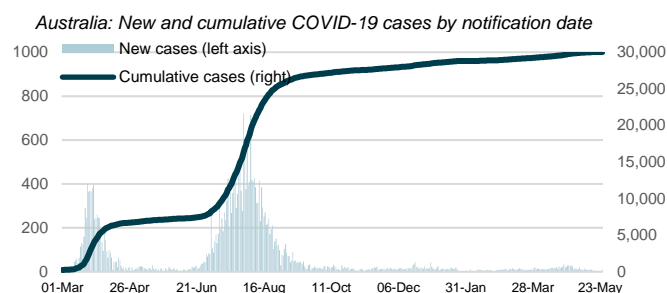
# COVID-19 Client Bulletin

Status as at: 26<sup>th</sup> May 2021

## Australia COVID-19 Snapshot

	Australia		United States	
	#	$\Delta^1$	#	$\Delta^1$
Confirmed Cases	30,029	2%	33,947,161	+5%
Deaths	910	0%	605,208	+5%
Deaths per 1M	35	0%	1,819	+4%
Testing rate per 1M	694,978	-	1,428,206	-

(1) change versus previous month



## Australia Clinical Trial Insights

<b>Feasibility</b>	<ul style="list-style-type: none"> <li>Majority of sites continue to be very interested in new studies</li> </ul>
<b>Ethics and Governance</b>	<ul style="list-style-type: none"> <li>Review and approval of clinical trials are continuing as scheduled.</li> <li>All submissions completed electronically, and legal documents e-signed</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>90% of the Top 10 sites are open for recruitment and 100% of Top 10 sites are open for SIVs for new studies</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>Most Top 10 sites are open to subject visits with ongoing social distancing measures</li> <li>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</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>Most sites are now open to onsite monitoring</li> <li>Novotech is deploying our regionally based CRA teams to ensure continuity with monitoring if local monitors are mandated by the sites</li> </ul>
<b>IP Supply and delivery</b>	<ul style="list-style-type: none"> <li>Passenger jet volume increasing to normal levels with normal operation of air couriers and local delivery</li> <li>Contingency in place to proactively ensure sufficient IP stock in the country to mitigate any delays with IP supply chain, if necessary</li> <li>Multiple vendors available for Direct to Patient IP delivery and home IP administration, where appropriate</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>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</li> <li>Electronic signature widely accepted</li> <li>Sites, Industry, Health Authority and National HRECs coordinating activities to ensure subject safety and trial continuity</li> <li>100% of Novotech staff can work remotely with office access if required. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation</li> <li>A travel bubble between Australia and New Zealand is now open with no quarantine required in either country</li> </ul>
<b>COVID-19 Trials</b>	<ul style="list-style-type: none"> <li>High levels of investigator interest, institutional support, and acceleration of processes from Ethics/regulatory authorities</li> <li>Final protocol to site activation estimated to be 3-4 weeks.</li> </ul>

## Top 10 sites: High level status

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
Westmead Hospital	Available	Available (exceptions)	On hold (exceptions)	Available	Available onsite	Expedited
Monash Hospital	Available	By video	Available (exceptions)	Available	Available onsite	Expedited
The Royal Melbourne	Available	By video	Available	Available	Available onsite	Expedited
Nucleus Network Ltd	Available	Available	Available	Available	Available onsite	Only vaccine trials expedited
Royal Adelaide Hospital	Available	Available	Available	Available	Available onsite	Expedited
The Alfred Hospital	Available	Available	Available	Available	Available onsite	Expedited
Austin Hospital	Available	By video	Available	Available	Available onsite	Requires exec approval
Royal Prince Alfred Hospital	Available	Available	Available	Available	Available onsite	Expedited
Linear Clinical Research	Available	Available	Available	Available	Available onsite	Only vaccine trials expedited
St Vincent's (Melbourne)	Available	Available	Available except for Gastro	Remote visits	Available onsite	On Hold

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

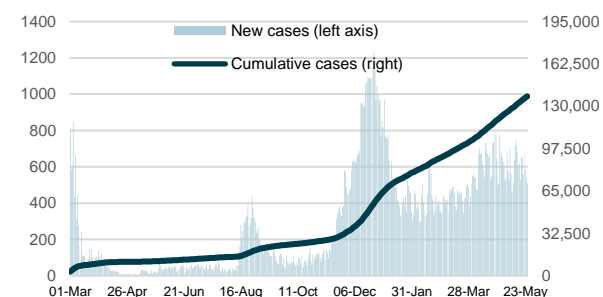
Sources: Worldometer, Ourworldindata.org, health.gov.au

## South Korea COVID-19 Snapshot

	South Korea		United States	
	#	$\Delta^1$	#	$\Delta^1$
Confirmed Cases	137,682	+22%	33,947,161	+5%
Deaths	1,940	+8%	605,208	+5%
Deaths per 1M	38	+9%	1,819	+4%
Testing rate per 1M	187,676	-	1,428,206	-

(1) change versus previous month

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



## South Korea Clinical Trial Insights

<b>Feasibility</b>	<ul style="list-style-type: none"> <li>Majority of sites continue to be very interested in new studies</li> </ul>
<b>Ethics and Governance</b>	<ul style="list-style-type: none"> <li>Review and approval of non-COVID-19 clinical trials are continuing as scheduled</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>Clinical trial sites are open, and recruitment is ongoing at all trial sites</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>Subject visits are available at all sites with social distancing measures implemented</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>Monitoring visits are permitted at all top sites but very competitive monitoring room booking found with limited capacity</li> </ul>
<b>IP Supply and delivery</b>	<ul style="list-style-type: none"> <li>Normal operation of air couriers and local delivery</li> <li>Contingency in place ensure sufficient IP stock in the country to mitigate any delays with international IP supply chain</li> <li>Multiple vendors available for direct to patient IP delivery as per MFDS guideline</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>Electronic signature accepted</li> <li>Sites, Industry, Health Authority and ECs coordinating activities to ensure subject safety and trial continuity</li> <li>100% of Novotech staff can work remotely with office access if required. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation</li> </ul>
<b>COVID-19 Trials</b>	<ul style="list-style-type: none"> <li>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</li> <li>High levels of investigator interest and institutional support to participate in COVID-19 trials</li> <li>Currently there are 49 COVID-19 trials approved in South Korea. Novotech is involved on two of these projects</li> <li>7 Covid-19 new drug approval by MFDS</li> <li>5 vaccines (2 AstraZeneca, Pfizer, Janssen, Moderna), 2 treatments (Gilead, Celltrion)</li> </ul>

## Top 10 sites: High level status

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

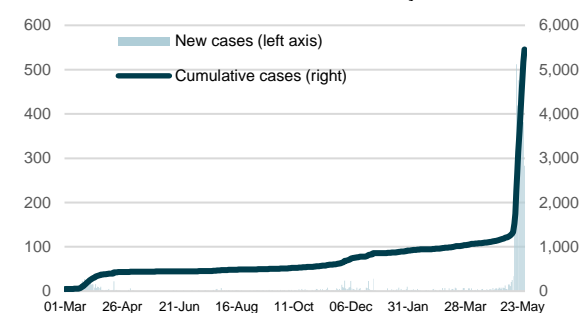
**Novotech monitors activity for all sites. Please contact your project manager for an update**

## Taiwan COVID-19 Snapshot

	Taiwan		United States	
	#	$\Delta^1$	#	$\Delta^1$
Confirmed Cases	5,456	+410%	33,947,161	+5%
Deaths	35	+218%	605,208	+5%
Deaths per 1M	1	+100%	1,819	+4%
Testing rate per 1M	25,608	-	1,428,206	-

(1) change versus previous month

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



## Taiwan Clinical Trial Insights

<b>Feasibility</b>	<ul style="list-style-type: none"> <li>All feasibility-related activities have been put on-hold since 17-May-2021 due to limited availability and resources from local sites and investigators.</li> </ul>
<b>Ethics and Governance</b>	<ul style="list-style-type: none"> <li>Review and approval of clinical trials are continuing as scheduled</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>Sites are open for recruitment to most trials with below exceptions:                             <ul style="list-style-type: none"> <li>NTUH, recruitment on hold for the studies handled by clinical trial center (CTC) and chest.</li> <li>CGMH-LK, CGMH-KS recruitment on hold for all studies.</li> <li>TPVGH recruitment on hold for studies handled by ONC and GS (breast cancer)</li> <li>KMUH recruitment on hold for the studies conducted by Dr. Wan-Long Chuang and Dr. Jee-Fu Huang. (Division of Hepatobiliary and Pancreatic Medicine.</li> <li>TSGH recruitment on hold for CTC handled studies</li> </ul> </li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>Sites are open for subject visits to occur with below exceptions:                             <ul style="list-style-type: none"> <li>TPVGH: The participants who live in high-risk areas</li> <li>NTUH: The studies conducted in Division of Nephrology might be impacted.</li> </ul> </li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>On site monitoring visits for all Taiwan sites have been put on hold.</li> </ul>
<b>IP Supply and delivery</b>	<ul style="list-style-type: none"> <li>No impact and the IP supply chain is operating with no restrictions</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>100% of Novotech staff can work remotely with office access if required</li> <li>State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation</li> <li>Electronic signatures are now accepted at some sites, however, will require wet-ink signatures when usual practices resume</li> </ul>
<b>COVID-19 Trials</b>	<ul style="list-style-type: none"> <li>High levels of interest, institutional support, and acceleration of processes from Ethics/regulatory authorities for COVID-19 vaccine trials</li> </ul>

## Top 10 sites: High level status

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
National Taiwan University	Available	On hold	Available (exceptions)	Available (exceptions)	On hold	Expedited
China Medical University	Available	On hold	Available	Available	On hold	Expedited
Chang Gung Memorial Hospital-Linko	Available	On hold	On hold	Available	On hold	Expedited
Taipei Veterans General	Available	On hold	Available (exceptions)	Available (exceptions)	On hold	Expedited
Chang Gung Memorial Hospital Kaohsiung	Available	On hold	On hold	Available	On hold	Expedited
Kaohsiung Medical University Hospital	Available	On hold	Available (exceptions)	Available	On hold	Expedited
Tri-service General Hospital	Available	On hold	Available (exceptions)	Available	On hold	Expedited
Chung Shan Medical University Hospital	Available	On hold	Available	Available	On hold	Expedited
Changhua Christian Hospital	Available	On hold	Available	Available	On hold	Expedited
Chi Mei Medical Center	Available	On hold	Available	Available	On hold	Expedited
Taichung Veterans General	Available	On hold	Available	Available	On hold	Expedited

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

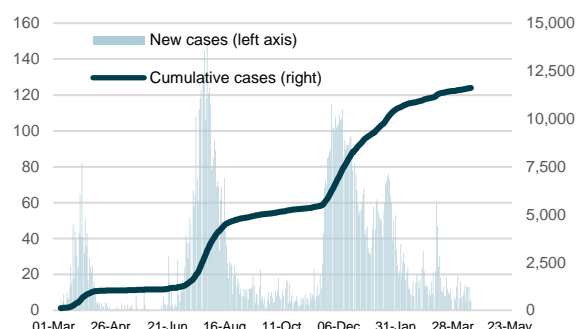
Sources: Worldometer, Ourworldindata.org

## Hong Kong COVID-19 Snapshot

	Hong Kong		United States	
	#	$\Delta^1$	#	$\Delta^1$
Confirmed Cases	11,836	+2%	33,947,161	+5%
Deaths	210	0%	605,208	+5%
Deaths per 1M	28	0%	1,819	+4%
Testing rate per 1M	1,965,346	-	1,428,206	-

(1) change versus previous month

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



## Hong Kong Clinical Trial Insights

<b>Feasibility</b>	<ul style="list-style-type: none"> <li>Majority of sites continue to be very interested in new studies</li> </ul>
<b>Ethics and Governance</b>	<ul style="list-style-type: none"> <li>Review and approval of non-COVID-19 clinical trials are continuing as scheduled</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>All top 10 sites are open for recruitment</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>In public sites, subject visits are proceeding with no changes required</li> <li>There has been limited impact for subjects that reside in China and seen in private sites and institutions</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>Most sites (public and private) are open for onsite monitoring visits</li> </ul>
<b>IP Supply and delivery</b>	<ul style="list-style-type: none"> <li>No impact and the IP supply chain is operating with no restrictions</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>Sites, Industry, Health Authority and ECs coordinating activities to ensure subject safety and trial continuity</li> <li>100% of Novotech staff can work remotely with office access if required. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation</li> <li>DoH approved Pfizer and Sinovac vaccines. Hong Kong citizen returning from China will not require quarantine</li> </ul>
<b>COVID-19 Trials</b>	<ul style="list-style-type: none"> <li>High levels of investigator interest, institutional support, and acceleration of processes from ethics/regulatory authorities for COVID-19 trials.</li> </ul>

## 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**

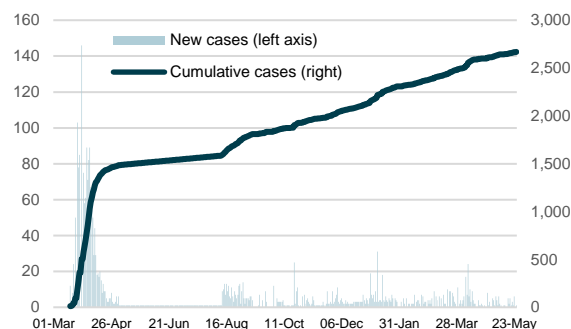
Sources: Worldometer, Ourworldindata.org

## New Zealand COVID-19 Snapshot

	New Zealand		United States	
	#	$\Delta^1$	#	$\Delta^1$
Confirmed Cases	2,669	+3%	33,947,161	+5%
Deaths	26	0%	605,208	+5%
Deaths per 1M	5	0%	1,819	+4%
Testing rate per 1M	422,203	-	1,428,206	-

(1) change versus previous month

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



## New Zealand Clinical Trial Insights

<b>Feasibility</b>	<ul style="list-style-type: none"> <li>Sites continue to be very interested in new studies</li> </ul>
<b>Ethics and Governance</b>	<ul style="list-style-type: none"> <li>Review and approval of non-COVID-19 clinical trials are continuing as previously scheduled for majority of sites</li> <li>Some delays have been observed as a result of an influx of trials into New Zealand</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>Sites continue to recruit patients across the country</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>Patient visits are ongoing, and sites are continuing to recruit to studies. Healthy volunteers are recruiting to studies</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>On-site monitoring visits are occurring across New Zealand</li> </ul>
<b>IP Supply and delivery</b>	<ul style="list-style-type: none"> <li>Tight controls at the borders continue. International commercial flights have been decreased; however, logistic companies continue to supply the country</li> <li>No restrictions on IP supply to sites by the drug depot</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>New Zealand has implemented Alert Level 1 for the whole country. At level 1 the country has no restrictions on gatherings or travel throughout the country. Regional travel including flying is permitted across the country. Controls at the borders remain for those entering New Zealand, including health screening and testing for all arrivals, and mandatory 14-day managed quarantine or isolation.</li> <li>A travel bubble involving isolation free travel between Australia and the Cook Island and New Zealand is open.</li> <li>Electronic signature widely accepted, now including Indemnities as the need for witness has been removed for the NZACRes template.</li> <li>100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation</li> <li>MedSafe has approved the Pfizer Covid-19 vaccine.</li> </ul>
<b>COVID-19 Trials</b>	<ul style="list-style-type: none"> <li>High levels of investigator interest, institutional support, and acceleration of processes from Ethics/regulatory authorities.</li> </ul>

## Top sites: High level status

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

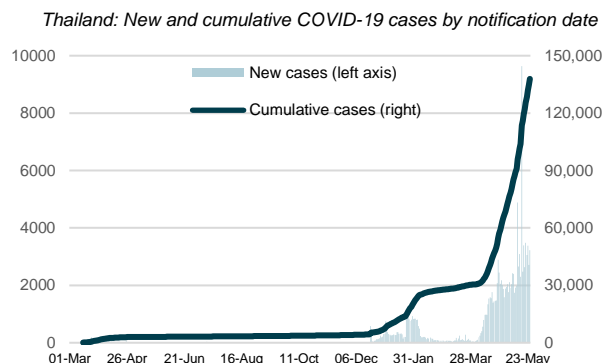
**Novotech monitors activity for all sites. Please contact your project manager for an update**

Sources: Worldometer, Ourworldindata.org

## Thailand COVID-19 Snapshot

	Thailand		United States	
	#	$\Delta^1$	#	$\Delta^1$
Confirmed Cases	137,894	+253%	33,947,161	+5%
Deaths	878	+800%	605,208	+5%
Deaths per 1M	12	+1100%	1,819	+4%
Testing rate per 1M	116,141	-	1,428,206	-

(1) change versus previous month



## Thailand Clinical Trial Insights

<b>Feasibility</b>	<ul style="list-style-type: none"> <li>Sites continue to be very interested in new studies</li> </ul>
<b>Ethics and Governance</b>	<ul style="list-style-type: none"> <li>Ethics Committees are accepting new projects online or via a portal as normal</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>Recruitment is on hold.</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>Sites are open for participant visits</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>Onsite monitoring visits are restricted from April 1<sup>st</sup> 2021</li> </ul>
<b>IP Supply and delivery</b>	<ul style="list-style-type: none"> <li>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</li> <li>Domestic flights operated with 50% flights/ routes reduced</li> <li>Marken vendor approved by QA and may be utilised by sites, if required, as a contingency</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>Novotech office in Bangkok is partially opened although 100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation. Mass COVID vaccine rollout is from June'21 onward.</li> </ul>
<b>COVID-19 Trials</b>	<ul style="list-style-type: none"> <li>HA and EC have an expedited COVID-19 trials review commitment of 8 weeks.</li> </ul>

## Top sites: High level status

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

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

Sources: Worldometer, Ourworldindata.org

# COVID-19 Client Bulletin

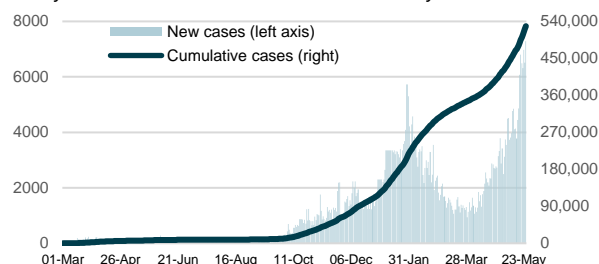
Status as at: 26<sup>th</sup> May 2021

## Malaysia COVID-19 Snapshot

	Malaysia		United States	
	#	$\Delta^1$	#	$\Delta^1$
Confirmed Cases	525,889	+42%	33,947,161	+5%
Deaths	2,369	+74%	605,208	+5%
Deaths per 1M	72	+71%	1,819	+4%
Testing rate per 1M	348,194	-	1,428,206	-

(1) change versus previous month

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



## Malaysia Clinical Trial Insights

<b>Feasibility</b>	<ul style="list-style-type: none"> <li>Majority of sites continue to be very interested in new studies however some delays in response are expected</li> </ul>
<b>Ethics and Governance</b>	<ul style="list-style-type: none"> <li>EC and HA review ongoing as per schedule now.</li> <li>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</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>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</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>Most sites remain open for subject visits, subject to Principal Investigator's discretion/ Hospital's direction</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>Onsite monitoring visits are limited, subject to Principal Investigator's discretion/ Hospital's direction</li> <li>Remote monitoring is allowed at most sites, with remote SDV limited at certain sites.</li> </ul>
<b>IP Supply and delivery</b>	<ul style="list-style-type: none"> <li>No restrictions on IP supply to sites by the drug depot</li> <li>DTP vendor approved by QA and may be utilised by sites, if required, as a contingency</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>The Malaysian government has imposed Movement Control Order (MCO) nationwide from 12 May until 7 June, 2021. All businesses are allowed to operate as usual, subject to compliance to SOPs.</li> <li>No interstate and inter-district travel is allowed currently</li> <li>100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation</li> </ul>
<b>COVID-19 Trials</b>	<ul style="list-style-type: none"> <li>HA and EC expedite COVID-19 trials on a case by case basis</li> <li>Currently Malaysia is participating in the WHO SOLIDARITY trial, with 9 sites, and a phase 3 COVID vaccine trial with 9 sites.</li> </ul>

## 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	Available	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	Available	Available	Available	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**

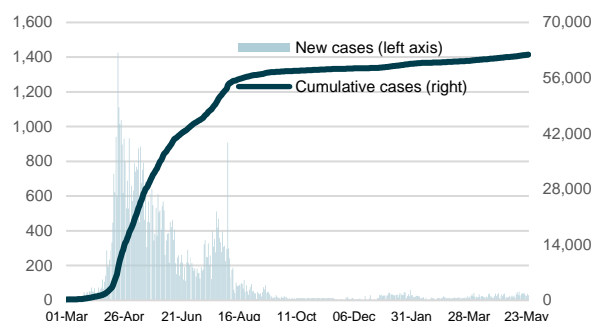
Sources: Worldometer, Ourworldindata.org

## Singapore COVID-19 Snapshot

	Singapore		United States	
	#	$\Delta^1$	#	$\Delta^1$
Confirmed Cases	61,890	2%	33,947,161	+5%
Deaths	32	7%	605,208	+5%
Deaths per 1M	5	0%	1,819	+4%
Testing rate per 1M	1,877,934	-	1,428,206	-

(1) change versus previous month

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



## Singapore Clinical Trial Insights

<b>Feasibility</b>	<ul style="list-style-type: none"> <li>Majority of sites continue to be very interested in new studies however some delays in response are expected</li> </ul>
<b>Ethics and Governance</b>	<ul style="list-style-type: none"> <li>EC and HA review ongoing as per schedule</li> <li>Singapore HA has released guidance on conduct of clinical trials in relation to the COVID-19 situation</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>Recruitment is on hold for most of the sites</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>Subject visits ongoing per normal</li> <li>If remote study visits are to be implemented, this must be notified to HA prior to implementation</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>Onsite monitoring visits are not allowed until further notice</li> </ul>
<b>IP Supply and delivery</b>	<ul style="list-style-type: none"> <li>No restrictions for IP supply to sites by drug depot</li> <li>DTP vendor approved by QA and may be utilised by sites if required</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>Work from home as default from 16 May 2021 – 13 June 2021. Companies should also continue to conduct virtual meetings as far as possible 100% of Novotech staff can work remotely with office access if required. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation</li> </ul>
<b>COVID-19 Trials</b>	<ul style="list-style-type: none"> <li>HA and EC may review COVID-19 trials on expedited basis, on a case-by-case basis</li> <li>Currently there are three COVID-19 trials approved in Singapore and 1 COVID vaccine trial.</li> </ul>

## 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)	On-hold	Available	On-hold	Expedited
Singapore General Hospital	Available	online (if pre-arranged)	On-hold	Available	On-hold	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
Kho 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**

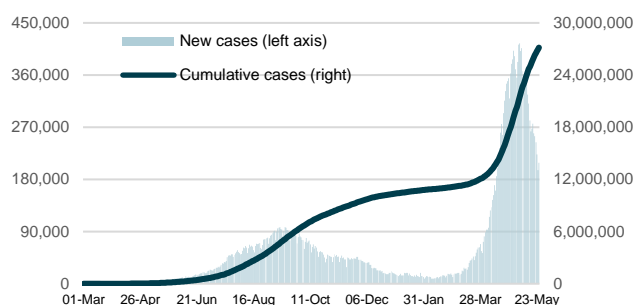
Sources: Statista, Worldometer, Ourworldindata.org

## India COVID-19 Snapshot

	India		United States	
	#	$\Delta^1$	#	$\Delta^1$
Confirmed Cases	27,157,795	+90%	33,947,161	+5%
Deaths	311,421	+79%	605,208	+5%
Deaths per 1M	224	+79%	1,819	+4%
Testing rate per 1M	238,905	-	1,428,206	-

(1) change versus previous month

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



## India Clinical Trial Insights

<b>Feasibility</b>	<ul style="list-style-type: none"> <li>Feasibilities are now progressing normally</li> </ul>
<b>Ethics and Governance</b>	<ul style="list-style-type: none"> <li>Most of the ethics committees are operating and reviewing clinical trials normally</li> <li>Ethics committees are also advised by Indian Council of Medical Research to review COVID19 trials in expedited manner</li> <li>Indian Council of Medical Research also released draft guidance to allow consenting through e-mail or text messages</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>New patient recruitment is affected as many sites are converted to COVID care centers</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>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 arranged using ambulances</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>Onsite monitoring visits are possible but depending upon approval from the site. These are largely affected.</li> <li>All top biotech sites allow for remote monitoring.</li> </ul>
<b>IP Supply and delivery</b>	<ul style="list-style-type: none"> <li>IP supply chain is functioning and allow to deliver IP to hospitals as well as directly to participants' home</li> <li>Major IP storage and distribution companies are operating normally. Some states such as North East, Tamilnadu are closed for interstate transport so shipments may get affected</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>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</li> <li>100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation</li> </ul>
<b>COVID-19 Trials</b>	<ul style="list-style-type: none"> <li>Regulatory submissions for all trials are conducted online</li> <li>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</li> </ul>

## Top 10 sites: High level status

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
King George's Medical Univ.	Available	Available	On -hold	Available	Remote monitoring	Several studies ongoing
Ruby Hall Clinical Services	Available	Available	On -hold	Available	Remote monitoring	Several studies ongoing
K.L.E.S. Dr. Prabhakar Kore Hospital	Available	Available (remotely)	On -hold	Available	Remote monitoring	-
King George Hospital Visakhapatnam	Available	Available partially	On -hold	IP is been dispensed via courier	Remote monitoring	Several studies in review
Sir Ganga Ram Hospital	Available	Available partially	On -hold	IP can be dispensed via courier	Remote monitoring	Several studies in review
Postgraduate Institute of Medical Education and Research Chandigarh	Available	Available (remotely)	On -hold	Available	Remote monitoring	-
Curie Manavata Cancer Centre	Available	Available partially	On -hold	Available	Remote monitoring	-
Deenanath Mangeshkar Hospital	Available	Available partially	On -hold	Available	Remote monitoring	Several studies in review
B J Medical College & Sassoon Hospital, Pune	Available	Available	On -hold	IP can be dispensed via courier	Remote Monitoring	Several studies in review

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

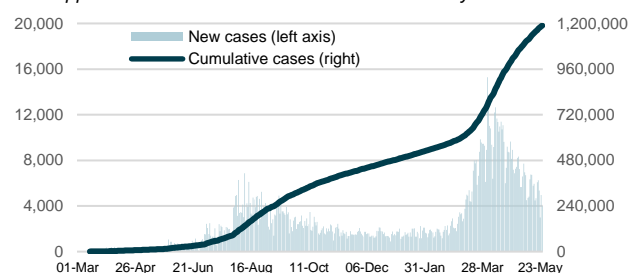
Sources: Worldometer, Ourworldindata.org

## The Philippines COVID-19 Snapshot

	The Philippines		United States	
	#	$\Delta^1$	#	$\Delta^1$
Confirmed Cases	1,188,672	+30%	33,947,161	+5%
Deaths	20,019	+27%	605,208	+5%
Deaths per 1M	181	+28%	1,819	+4%
Testing rate per 1M	118,019	-	1,428,206	-

(1) change versus previous month

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



## The Philippines Clinical Trial Insights

<b>Feasibility</b>	<ul style="list-style-type: none"> <li>Majority of sites continue to be interested in new studies however some delays in response are expected</li> </ul>
<b>Ethics and Governance</b>	<ul style="list-style-type: none"> <li>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</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>Recruitment in studies is open under General Community Quarantine status. However, recruitment in studies targeting &lt;18yo or &gt;60yo population may require special arrangement due to general restrictions for this age group to go out of their residence.</li> <li>Sites have resumed clinical trial activities, however, increase in COVID cases admission in hospital since March 2021 may delay the site's ability to deliver study activities.</li> <li>Ethics require sponsor to cover for PPE cost of subjects in clinical trial &amp; site staff.</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>We are seeing a number of IRB requiring increase of subject travel budget to cover for special transport arrangement going to the site.</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>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.</li> <li>Sites are open to support remote monitoring however this would be assessed on a case-by-case basis.</li> </ul>
<b>IP Supply and delivery</b>	<ul style="list-style-type: none"> <li>Domestic flights have resumed but movement location with different quarantine restriction may cause delay. Inbound flights still be limited but cargo flights unhampered.</li> <li>Local logistics providers can support distribution of IP to site or direct-to-patient delivery.</li> <li>DTP vendor approved by QA and may be utilised by sites, if required, as a contingency</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>General Community Quarantine status implemented in Metro Manila and 4 other nearby provinces until 31May2021 but with heightened restriction limiting travel in/out of Metro Manila to essential travel only (work related travel is allowed subject to compliance to border requirements including negative RT-PCR test and travel pass approval).</li> <li>100% of Novotech staff can work remotely. State-of-the-art IT infrastructure with ISO 27001 Information Security accreditation</li> <li>Strong interest in Covid-19 trials and vaccine studies due to high of cases in Metro Manila. Metro Manila hospitals are at full capacity for moderate-severe COVID admissions since April, recruitment for mild to moderate indications is affected. Philippines participating in WHO Solidarity I (treatment) and Solidarity II (vaccine) trials.</li> </ul>
<b>COVID-19 Trials</b>	<ul style="list-style-type: none"> <li>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.</li> <li>Several investigators indicated interest in Covid-19 MAb treatment trial and Covid-19 vaccine trial.</li> </ul>

## 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 (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Expedited
Makati Medical Center	Available	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Expedited
St Luke's Medical Center (SLMC)	Available	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Expedited
Quezon City National Kidney & Transplant Institute (NKTi)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Expedited
Philippine General Hospital	Available	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Expedited
Baguio General Hospital	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Expedited
Manila Doctors Hospital	Available	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Expedited
Perpetual Succour Hospital	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	On-hold	Expedited

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

Sources: Worldometer, Ourworldindata.org