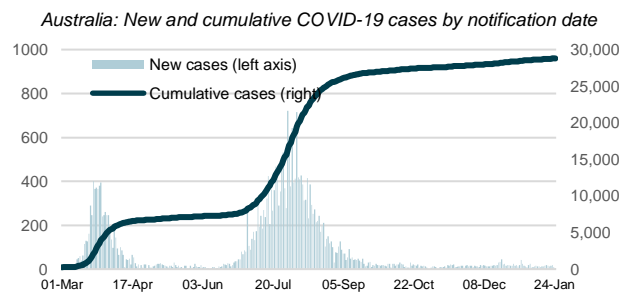


Status as at: 25<sup>th</sup> January 2021

## Australia COVID-19 Snapshot

	Australia		United States	
	#	Δ <sup>1</sup>	#	Δ <sup>1</sup>
<b>Confirmed Cases</b>	28,785	2%	26,166,201	+34%
<b>Deaths</b>	909	0%	439,517	+30%
<b>Deaths per 1M</b>	35	0%	1,323	+30%
<b>Testing rate per 1M</b>	498,911	-	916,573	-

(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>Bellberry (private EC): continues to operate remotely and is fully operational whilst supporting fast-tracked COVID-19 studies</li> <li>Public sites: all meetings conducted virtually and maintaining the pre-planned 2021 timetables. 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 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>80% of all sites are open to either onsite or remote monitoring</li> <li>Novotech is working closely with sites with a focus on re-establishing site activities or return to remote monitoring as required</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>Significant reduction in passenger jet volume but 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</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 Pfizer vaccine for deployment in February</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> </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 (Top 10 sites in Australia represent 33% of biotech activity)

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

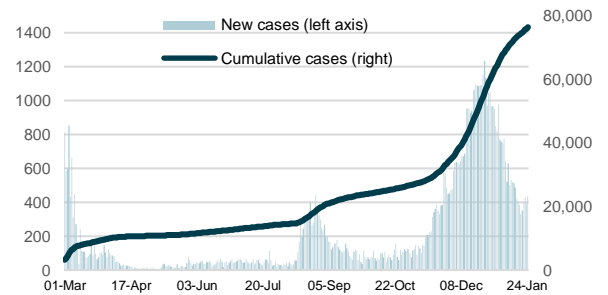
Status as at: 25<sup>th</sup> January 2021

## South Korea COVID-19 Snapshot

	South Korea		United States	
	#	Δ <sup>1</sup>	#	Δ <sup>1</sup>
<b>Confirmed Cases</b>	76,429	+40%	26,166,201	+34%
<b>Deaths</b>	1,378	+78%	439,517	+30%
<b>Deaths per 1M</b>	27	+78%	1,323	+30%
<b>Testing rate per 1M</b>	106,624	-	916,573	-

(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 now 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 now 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</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 41 COVID-19 trials approved in South Korea. Novotech is involved on two of these projects</li> </ul>

## Top 10 sites: High level status (Top 10 sites in South Korea represent 48% of biotech activity)

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
<b>Asan Medical Center</b>	Available	Available	Available	Available	Available	Expedited
<b>Samsung Medical Center</b>	Available	Available	Available	Available	Available (limited seats)	Expedited
<b>Seoul National University Hospital</b>	Available	Available	Available	Available	Available	Expedited
<b>Seoul National University Bundang</b>	Available	Available	Available	Available	Available	Expedited
<b>Severance Hospital, Yonsei University Health System</b>	Available	Available	Available	Available	Available	Expedited
<b>The Catholic University Of Korea Seoul St.Mary's Hospital</b>	Available	Available	Available	Available	Available	Expedited
<b>Pusan National University Hospital</b>	Available	Available	Available	Available	Available for NVT (under MOU)	Expedited
<b>Gachon University Gil Medical C.</b>	Available	Available	Available	Available	Available	Expedited
<b>Chonnam National University Hwasun Hospital</b>	Available	Available	Available	Available	Available	Expedited
<b>The catholic university of korea, st. Vincent hospital</b>	Available	Available	Available	Available	Available	Expedited

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

Sources: Worldometer, Ourworldindata.org

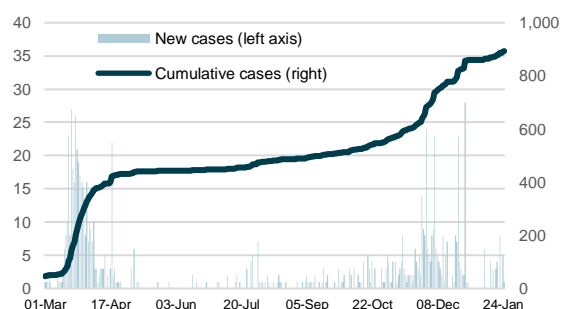
Status as at: 25<sup>th</sup> January 2021

## Taiwan COVID-19 Snapshot

	Taiwan		United States	
	#	Δ <sup>1</sup>	#	Δ <sup>1</sup>
Confirmed Cases	893	+14%	26,166,201	+34%
Deaths	7	0%	439,517	+30%
Deaths per 1M	0.3	0%	1,323	+30%
Testing rate per 1M	6,233	-	916,573	-

(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>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> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>Sites are open for recruitment to all trials</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>Sites are open for subject visits to occur</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>Monitoring visits are permitted</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 investigator interest, institutional support, and acceleration of processes from Ethics/regulatory authorities for COVID-19 trials</li> </ul>

## Top 10 sites: High level status (Top 10 sites in Taiwan represent 78% of biotech activity)

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

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

Sources: Worldometer, Ourworldindata.org

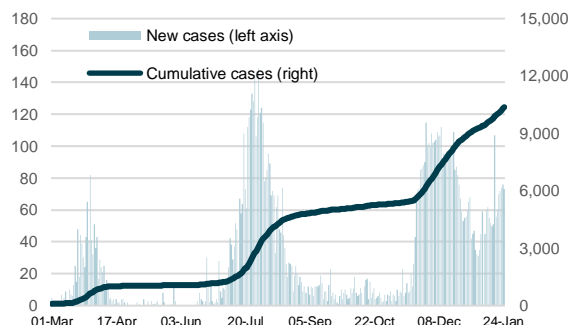
Status as at: 25<sup>th</sup> January 2021

## Hong Kong COVID-19 Snapshot

	Hong Kong		United States	
	#	Δ <sup>(1)</sup>	#	Δ <sup>(1)</sup>
<b>Confirmed Cases</b>	10,283	+21%	26,166,201	+34%
<b>Deaths</b>	175	+29%	439,517	+30%
<b>Deaths per 1M</b>	23	+29%	1,323	+30%
<b>Testing rate per 1M</b>	855,378	-	916,573	-

(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>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 investigator interest, institutional support, and acceleration of processes from ethics/regulatory authorities for COVID-19 trials</li> </ul>

## Top biotech sites: High level status (Top 10 sites in Hong Kong represent 100% of biotech activity)

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
<b>Queen Mary Hospital</b>	Available	Available	Available	Available	Available onsite	Expedited
<b>Prince of Wales Hospital</b>	Available	Available	Available	Available	Available onsite	Expedited
<b>Princess Margaret Hospital</b>	Available	Available	Available	Available	Available onsite	Expedited
<b>Queen Elizabeth Hospital</b>	Available	Available	Available	Available	Available onsite	Expedited
<b>Alice Ho Miu Ling Nethersole Hospital</b>	Available	Available	Available	Available	Available onsite	Expedited
<b>Tuen Mun Hospital</b>	Available	Available	Available	Available	Available onsite	Expedited
<b>Humanity &amp; Health Research Center</b>	Available	Available	Available	Available	Available onsite	na
<b>Pamela Youde Nethersole Eastern Hospital</b>	Available	Available	Available	Available	Available onsite	Expedited
<b>Hong Kong United Oncology</b>	Available	Available	Available	Available	Available onsite	na
<b>UNIMED Medical Institute</b>	Available	Available	Available	Available	Available onsite	na

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

Sources: Worldometer, Ourworldindata.org

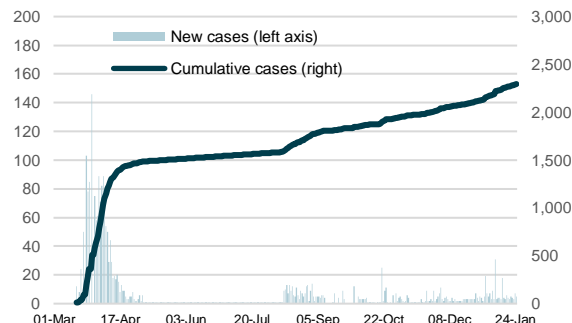
Status as at: 25<sup>th</sup> January 2021

## New Zealand COVID-19 Snapshot

	New Zealand		United States	
	#	$\Delta^1$	#	$\Delta^1$
<b>Confirmed Cases</b>	2,295	+8%	26,166,201	+34%
<b>Deaths</b>	25	0%	439,517	+30%
<b>Deaths per 1M</b>	5	0%	1,323	+30%
<b>Testing rate per 1M</b>	300,735	-	916,573	-

(1) change versus previous month

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



## New Zealand Clinical Trial Insights

- Feasibility**
  - Sites continue to be very interested in new studies
- Ethics and Governance**
  - Review and approval of non-COVID-19 clinical trials are continuing as previously scheduled for majority of sites
  - Some delays have been observed as a result of staff redeployment, an influx of applications for COVID-19 trials and amendments to existing trials
- Recruitment**
  - Sites continue to recruit patients across the country
- Participant visits**
  - Patient visits are ongoing, and sites are continuing to recruit to studies. Healthy volunteers are recruiting to studies
- Monitoring**
  - On-site monitoring visits are occurring across New Zealand
- IP Supply and delivery**
  - Tight controls at the borders continue. International commercial flights have been decreased; however, logistic companies continue to supply the country
  - No restrictions on IP supply to sites by the drug depot
- General**
  - New Zealand has implemented Alert Level 1 for the whole country on Oct 8<sup>th</sup>. 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.
  - 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 will be reviewing the Pfizer Covid-19 vaccine application on Feb 2<sup>nd</sup> 2021
- COVID-19 Trials**
  - High levels of investigator interest, institutional support, and acceleration of processes from Ethics/regulatory authorities

## Top sites: High level status (Top 10 sites in New Zealand represent 56% of biotech activity)

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

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

Sources: Worldometer, Ourworldindata.org

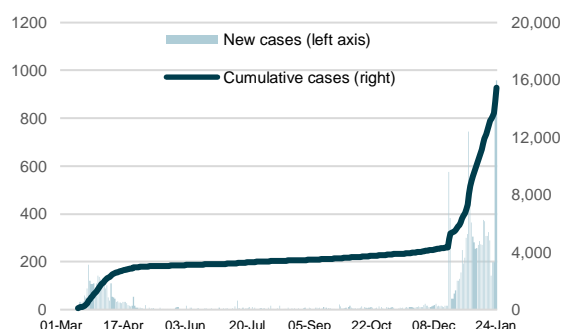
Status as at: 25<sup>th</sup> January 2021

## Thailand COVID-19 Snapshot

	Thailand		United States	
	#	$\Delta^1$	#	$\Delta^1$
Confirmed Cases	15,465	+162%	26,166,201	+34%
Deaths	76	27%	439,517	+30%
Deaths per 1M	1	27%	1,323	+30%
Testing rate per 1M	17,423	-	916,573	-

(1) change versus previous month

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



## 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
- Recruitment**
  - Recruitment is now available at most sites
- Participant visits**
  - Sites are open for participant visits
- Monitoring**
  - Onsite monitoring visits are restricted until Jan 31st 2021
- IP Supply and delivery**
  - 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 resumed on 1<sup>st</sup> May
  - Marken vendor approved by QA and may be utilised by sites, if required, as a contingency
- General**
  - 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
- COVID-19 Trials**
  - HA and EC have an expedited COVID-19 trials review commitment of 8 weeks

## Top sites: High level status (Top 10 sites in Thailand represent 59% of biotech activity)

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

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

Sources: Worldometer, Ourworldindata.org



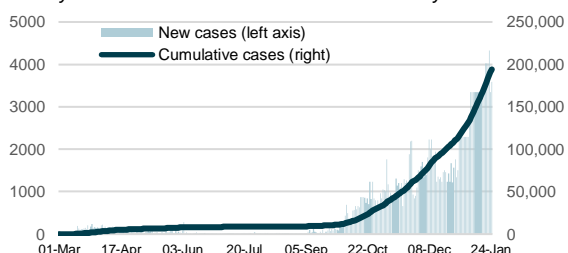
Status as at: 25<sup>th</sup> January 2021

## Malaysia COVID-19 Snapshot

	Malaysia		United States	
	#	Δ <sup>1</sup>	#	Δ <sup>1</sup>
<b>Confirmed Cases</b>	194,114	+91%	26,166,201	+34%
<b>Deaths</b>	707	+57%	439,517	+30%
<b>Deaths per 1M</b>	22	+57%	1,323	+30%
<b>Testing rate per 1M</b>	141,316	-	916,573	-

(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. Health Authority is prioritising COVID-19 applications during this period</li> <li>An expedited review will be given 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 not allowed at the moment.</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 (CMCO) until Feb 4<sup>th</sup> 2021 in almost all states in the country. Only 5 essential economic sectors allowed to operate: manufacturing; construction; service; trade and distribution; and plantations and commodities. Those in non-essential services are to work from home.</li> <li>No interstate and inter-district travel are allowed</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 (Top 10 sites in Malaysia represent 63% of biotech activity)

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
<b>University Malaya Medical C.</b>	Available	Available (remotely)	Available	Available	Remote Monitoring	Expedited
<b>Hospital Kuala Lumpur</b>	Available	Available (remotely)	Available	Available	Remote Monitoring	Expedited
<b>Hospital Pulau Pinang</b>	Available	Available (remotely)	Available	Available	Remote Monitoring	Expedited
<b>Hospital Ampang</b>	Available	Available (remotely)	Available	Available	Remote Monitoring	Expedited
<b>Hospital Umum Sarawak</b>	Available	Available (remotely)	Available	Available	Remote Monitoring	Expedited
<b>Hospital Raja Perempuan Zainab II</b>	Available	Available (remotely)	Available	Available	Remote Monitoring	Expedited
<b>Hospital Raja Permaisuri Bainun</b>	Available	Available (remotely)	Available	Available	Remote Monitoring	Expedited
<b>Hospital Serdang</b>	Available	Available (remotely)	Available	Available	Remote Monitoring	Expedited
<b>Hospital Sultan Ismail</b>	Available	Available (remotely)	Available	Available	Remote Monitoring	Expedited
<b>Hospital Tengku Ampuan</b>	Available	Available (remotely)	Available	Available	Remote Monitoring	Expedited

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

Sources: Worldometer, Ourworldindata.org

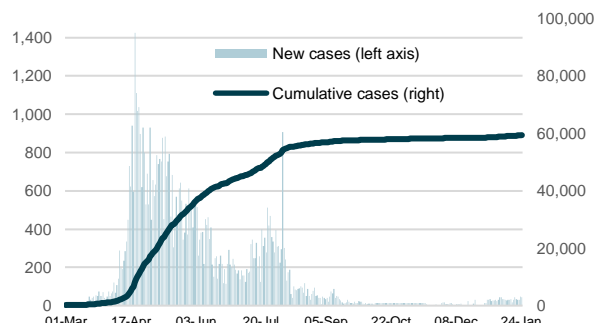
Status as at: 25<sup>th</sup> January 2021

## Singapore COVID-19 Snapshot

	Singapore		United States	
	#	Δ <sup>(1)</sup>	#	Δ <sup>(1)</sup>
<b>Confirmed Cases</b>	59,391	2%	26,166,201	+34%
<b>Deaths</b>	29	0%	439,517	+30%
<b>Deaths per 1M</b>	5	0%	1,323	+30%
<b>Testing rate per 1M</b>	1,074,652	-	916,573	-

(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 available for most 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 allowed if pre-arranged with Principal Investigator and Study Coordinator.</li> <li>Only monitors are allowed on site</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>Singapore government has implemented the post Circuit Breaker phase 3 on Dec 28<sup>th</sup> 2020. Essential businesses are back to normal and people are encouraged to work from home.</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>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 (Top sites in Singapore represent 100% of biotech activity)

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
<b>National University Hospital</b>	Available	Available (if pre-arranged)	Available	Available	Onsite (with pre-arrangement)	Expedited
<b>Singapore General Hospital</b>	Available	Available (if pre-arranged)	Available	Available	Onsite (with pre-arrangement)	Expedited
<b>Changi General Hospital</b>	Available	Available (if pre-arranged)	Available	Available	Onsite (with pre-arrangement)	Expedited
<b>National Cancer Centre</b>	Available	Available (if pre-arranged)	Available	Available	Onsite (with pre-arrangement)	-
<b>Raffles Hospital</b>	Available	Available (if pre-arranged)	Available	Available	Onsite (with pre-arrangement)	-
<b>Tan Tock Seng Hospital</b>	Available	Available (if pre-arranged)	Available	Available	Onsite (with pre-arrangement)	Expedited
<b>Khoo Teck Puat Hospital</b>	Available	Available (if pre-arranged)	Available	Available	Onsite (with pre-arrangement)	Expedited
<b>Curie Oncology</b>	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



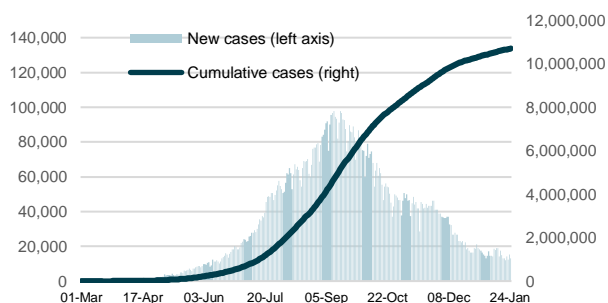
Status as at: 25<sup>th</sup> January 2021

## India COVID-19 Snapshot

	India		United States	
	#	Δ <sup>1</sup>	#	Δ <sup>1</sup>
<b>Confirmed Cases</b>	10,702,031	+5%	26,166,201	+34%
<b>Deaths</b>	153,885	+4%	439,517	+30%
<b>Deaths per 1M</b>	111	+4%	1,323	+30%
<b>Testing rate per 1M</b>	140,035	-	916,573	-

(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>Sites are now open as lockdown is only restricted to containment zones. There are still some restrictions on travel so patient recruitment may still be affected</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>A majority of top sites allow visits to occur</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>Onsite monitoring visits are possible but depending upon approval from the site</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</li> <li>Major IP storage and distribution companies are operating normally</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>India has implemented a lockdown which is restricted to specific containment zones, 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)</li> </ul>

## Top 10 sites: High level status (Top 10 sites in India represent 12% of biotech activity)

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

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

Sources: Worldometer, Ourworldindata.org

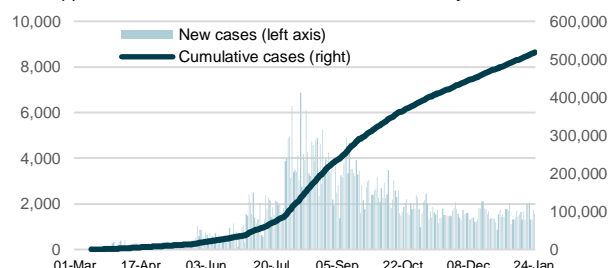
Status as at: 25<sup>th</sup> January 2021

## The Philippines COVID-19 Snapshot

	The Philippines		United States	
	#	Δ <sup>1</sup>	#	Δ <sup>1</sup>
<b>Confirmed Cases</b>	518,407	+11%	26,166,201	+34%
<b>Deaths</b>	10,481	+16%	439,517	+30%
<b>Deaths per 1M</b>	95	+16%	1,323	+30%
<b>Testing rate per 1M</b>	69,054	-	916,573	-

(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 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>Philippine FDA issued circular on Emergency Use Authorization for Covid-19 Vaccine in Dec 2020 with 21 days approval timeline.</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>Recruitments have resumed in Metro Manila, Cebu, and other sites located within the General Community Quarantine.</li> <li>Most sites have resumed clinical trial 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 now allowed at some sites</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. Inbound flights may 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 for Metro Manila extended to Jan 31st 2021</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>Strong interest in Covid-19 trials due to high of cases in Metro Manila. Philippines participating in WHO Solidarity I (treatment) and Solidarity II (vaccine) trials.</li> <li>COVID-19 trials will be treated as priority by Philippine FDA and the Single Joint Research Ethics Board (SJREB)</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 (Top 10 sites in The Philippines represent 46% of biotech activity)

	Ethics/ Gov	Site Initiation	Recruitment	Participant visits	Monitoring	COVID-19 trials
<b>Davao Doctors Hospital</b>	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available	Available (with exceptions)	Expedited
<b>De La Salle Health Science Institute</b>	Available	Available	Available	Available	Available (with exceptions)	Expedited
<b>Makati Medical Center</b>	Available	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Expedited
<b>St Luke's Medical Center (SLMC) Quezon City</b>	Available	Available (with exceptions)	Available (with exceptions)	Available	Available (with exceptions)	Expedited
<b>National Kidney &amp; Transplant Institute (NKTI)</b>	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Expedited
<b>Philippine General Hospital</b>	Available	Available	Available	Available	Available	Expedited
<b>Baguio General Hospital</b>	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Expedited
<b>Manila Doctors Hospital</b>	Available	Available	Available	Available	Available	Expedited
<b>Perpetual Succour Hospital</b>	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Available (with exceptions)	Expedited

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

Sources: Worldometer, Ourworldindata.org