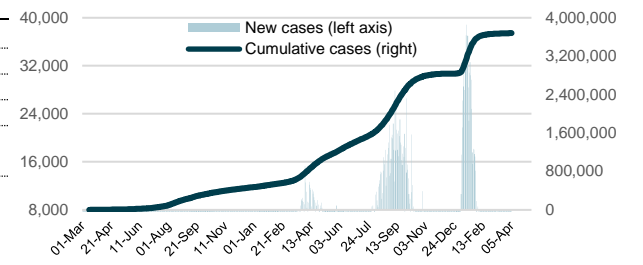


# COVID-19 Client Bulletin

Status as at: 5<sup>th</sup> April 2022

	The Philippines		United States	
	#	Δ <sup>1</sup>	#	Δ <sup>1</sup>
<b>Confirmed Cases</b>	3,679,983	13%	81.9m	+21%
<b>Deaths</b>	59,370	12%	1,009,390	+15%
<b>Deaths per 1M</b>	529	12%	3,018	+15%
<b>Testing rate per 1M</b>	258,800	-	2,952,541	-
<b>Population with at least one vaccination</b>	~51%		~77%	

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



(1) change versus previous month

## 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.</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 8 COVID19 vaccines given with EUA in the Philippines. FDA has priority pathway for COVID-19 treatment (30d approval) and vaccine trials (40d approval). COVID-19 treatment and vaccine trial require monthly and quarterly progress status notification to FDA.</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>Recruitment is open in most sites as community quarantine classification is down to Alert level 1 (low case transmission). However, mask is still mandatory in public place/transportation and enclosed places and physical distancing is still required. Thus, participants require pre-arranged schedule prior to site visit to ensure there is no crowding at site. Ethics require sponsor to cover for PPE cost of subjects in clinical trial &amp; site staff.</li> </ul>
<b>Participant visits</b>	<ul style="list-style-type: none"> <li>We are seeing several IRB requiring increases in subject travel budgets 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 for COVID exposure for Novotech staff. Travel outside Metro Manila (to provincial sites) may be subjected to local city travel protocol especially in locations where there is increase in reported COVID cases. Sites are open to support remote monitoring however this would be assessed on a case-by-case basis.</li> </ul>
<b>IP Supply and delivery</b>	<ul style="list-style-type: none"> <li>Domestic and international flights are normal operations Inbound flights still limited but cargo flights unhampered. Domestic travellers who are fully immunized against COVID-19 vaccine can travel freely without need for quarantine. Foreign inbound traveller needs to be fully immunized and with negative RT-PCR 48-hrs prior to arrival to enter the Philippines. There is no quarantine requirement for fully immunized travellers.</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>Metro Manila eased to Alert #1 status from 15 March 2022 100% of Novotech staff have received their full COVID-19 vaccination, majority have received their booster shot.</li> <li>Novotech staff can work remotely but Novotech office is at 100% capacity. 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>Government keen on COVID-19 vaccine studies involving vulnerable population e.g., paediatric and with co-morbidities. COVID-19 trials on mild indication requiring hospital admission are not feasible as these cases are sent on government isolation facilities or home quarantine. Philippines participating in WHO Solidarity Plus (treatment) and Solidarity II (vaccine) trials.</li> <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 regulatory approval takes 40d turnaround time.</li> <li>COVID-19 vaccination in adults in Metro Manila have reached more than 94%. The Philippine government aggressive with the vaccination of 12-17 years old since October2021 and began vaccination of children 5 to 11 years old in February 2022.</li> </ul>

## Top 10 sites: High level status

	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 (with exceptions)	Available	Expedited
<b>De La Salle Health Science Institute</b>	Available	Available	Available	Available	Available	Expedited
<b>Makati Medical Center</b>	Available	Available	Available	Available	Available	Expedited
<b>St Luke's Medical Center (SLMC) Quezon City</b>	Available	Available	Available	Available	Available	Expedited
<b>National Kidney &amp; Transplant Institute (NKT)</b>	Available	Available	Available	Available	Available	Expedited
<b>Philippine General Hospital</b>	Available	Available	Available	Available	Available	Expedited
<b>Baguio General Hospital</b>	Available	Available	Available	Available	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	Expedited

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

Sources: Worldometer, Ourworldindata.org

## China COVID-19 Snapshot

# COVID-19 Client Bulletin

Status as at: 5<sup>th</sup> April 2022

**China**

**United States**

