PCRP
Philippine Clinical Research Professionals Inc.

# COVID-19 CONTINGENCY GUIDANCE

**DEAR PCRP MEMBERS,**

First of all, I would like to thank you for keeping in touch by joining the PCRP Viber Community and supporting our ongoing fund drive. Members connecting with each other is a testament of our collaboration and solidarity. We should continue to share ideas, concerns and uplift each other during this time of immense global challenge and altogether cushion the impact it brings to our industry.

Your PCRP Board and Honorary Members have been working hard, day and night to gather the various issues coming from you surrounding the present situation and the real-time challenges we are facing in the conduct of clinical trials in the Philippines.

Today, PCRP is releasing its first guidance document called **"COVID-19 Contingency Guidance from PCRP ver 19 March 2020"** which will be cascaded to all our members. This is a tool to help you in addressing the challenges related to study and site management activities. PCRP members may share this within their respective companies. As the situation now is very fluid, please take note that this document will be updated from time to time as we address real-time concerns.

PCRP is also engaging in dialogues with various stakeholders to find solutions to the other issues raised by our members that are still not covered by this first guidance document, so please stay connected with us.

This communique' will be sent to you through our PCRP website, PCRP company links and the PCRP Viber Community as updates become available.

Stay tuned! But more importantly, keep safe and healthy.

**YOURS TRULY,**

Rodmar C. Pulido

**Rodmar Pulido**
**PCRP President**

Released on 19 March 2020.

# COVID-19 Contingency Guidance from PCRP ver 19 Mar 2020

Prepared by

Philippine Clinical Research Professional, Inc. (PCRP)

# Philippines is under an Enhanced-Community Quarantine (ECQ) (lockdown) from 15 March to 14 April 2020

What does ECQ mean?

- Mandatory home quarantine
- Suspension of public mass transportation
- Regulation of goods and services

What does it mean for clinical trial delivery?

- Hospital resources diverted to COVID19 response
- Government agencies are on skeletal workforce
- Hospital OPD & Research site operations are suspended
- Site Staff cannot travel / restricted to access hospitals
- Patient cannot travel to the sites
- IP /Bio samples/Supply shipments are not assured

What are the implications on clinical trial activities?

- Postponement of SIV and onsite visits
- Interruption/ hold on recruitment
- Disruption of patient visits
- Delay in start-up activities
- Delay on review and approval of clinical trial documents

# Message from PCRP

- The **safety** of our clinical trial participants, clinical study site staff, clinical study ancillary personnel and clinical study monitors must be ensured at all times.
- Keep up to date on government proclamations by following DOH PH COVID 19 broadcasts and share these within your company.
- PCRP acknowledges that every company has its own business continuity guidelines, we ask that you share PCRP's guidance documents to your company for consideration.
- PCRP will collect and share information related to clinical trial industry matters and shall remain as your voice to relevant government agencies.

**The following slides are 2-fold.**

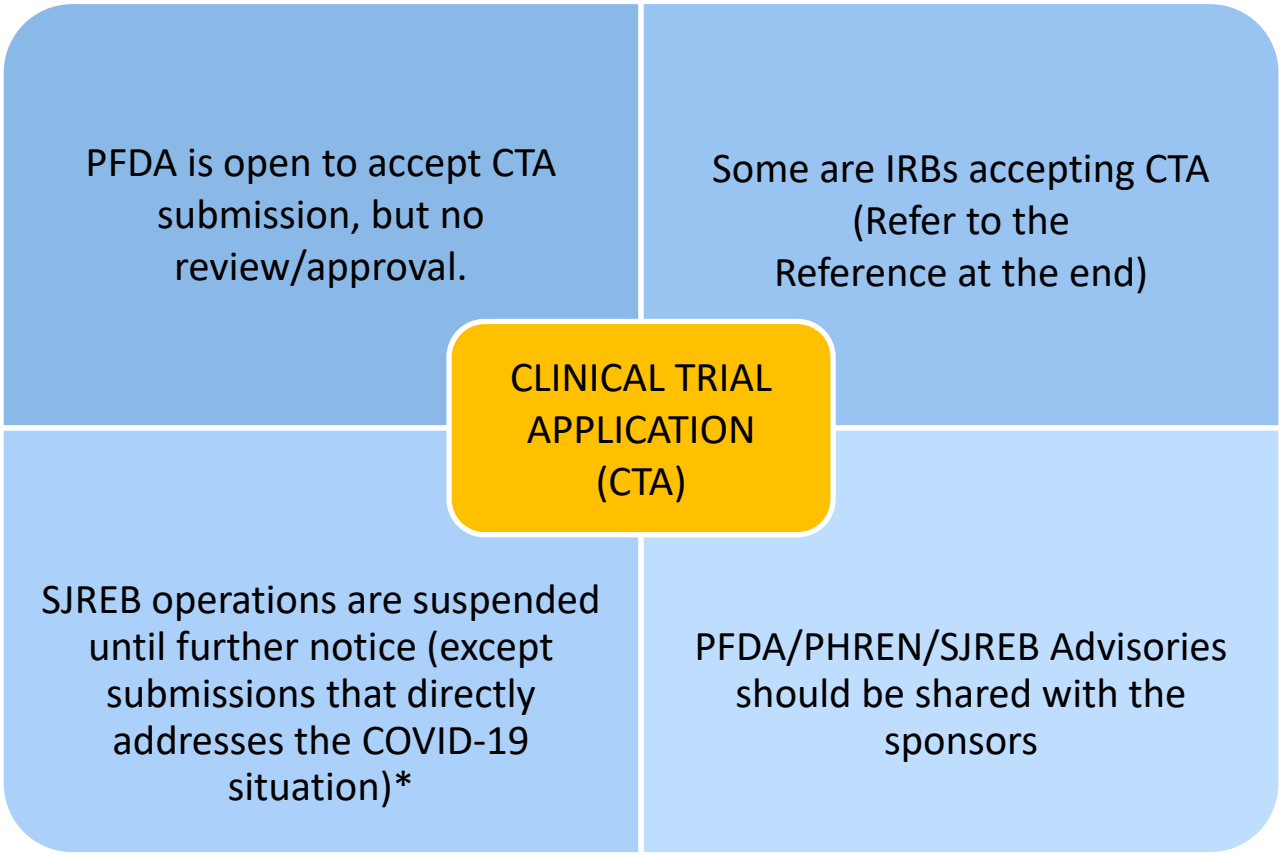
Due to limitations with the Luzon-wide lockdown, the following actions can be taken:

1. **Contingencies** – to address the current situation that directly impacts clinical trial activities.

2. **Mitigation Plans** - PCRP will engage with government and private agencies – PHREN, institutions/hospitals, vendors and suppliers to formulate the mitigation plans *(to follow)*

*This document will be updated as new information becomes available.*

# CONTINGENCY FOR STUDIES ON START-UP/MAINTENANCE PHASE




*Inform PCRP if company has intention to submit CTA to SJREB

# CONTINGENCY ON STUDIES FOR SIV

**Postpone Initiation Visit**

- Discuss with your PI
- Notify relevant hospital departments, as necessary
- Check impact on study contracts
- Keep sponsor updated on relevant developments

# CONTINGENCY FOR STUDIES ON ACTIVE RECRUITMENT

**Hold Recruitment**

- Discuss with PI & inform relevant offices (IRB, FDA, hospital departments)
- PI should notify active patients about the temporary stop in recruitment,

**Monitoring for Patient Safety by Study Site Staff must be in place**

- Encouraging patients of continued communication with site staff
- Reminding patients on the importance of reporting safety concerns
- Consider alternative to patient on-site visits such as telephone contacts
- Remind sites to document changes in investigational plan

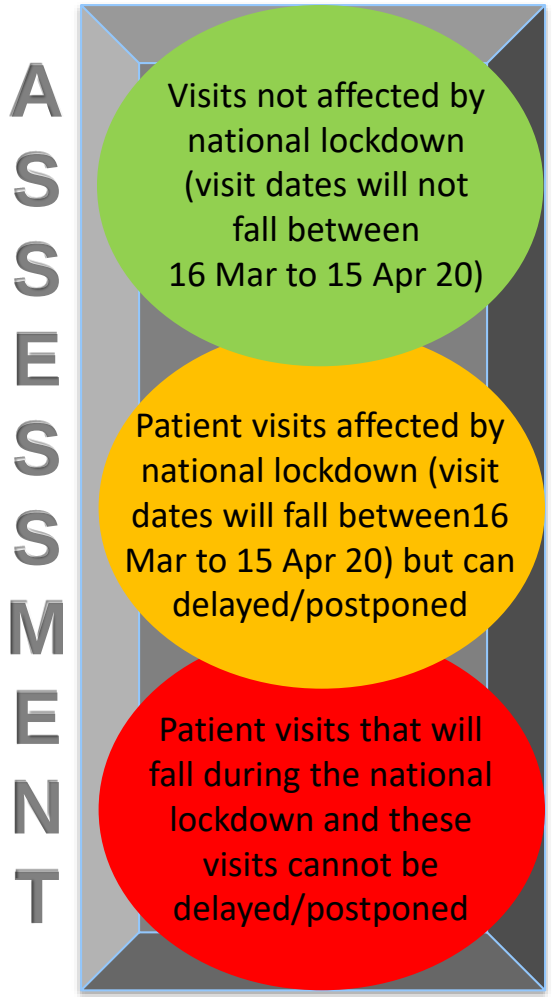
# CONTINGENCY ON STUDIES FOR ONSITE VISITS

**Postpone Onsite Visits**

- Discuss with your PI
- Consider remote monitoring, as applicable
- Document deviations to the monitoring plan
- Relevant training, basic checklist for remote monitoring
- Close coordination with study team
- Review company guidance and training

# ASSESSMENT TOOL FOR ONGOING STUDIES

This assessment is essential in determining risks and finding solutions to ensure patient safety and clinical trial delivery during this emergency. Clinical Operations Heads would have determined this and included in their country risk and mitigation logs.



## How Can We Help You?

We need data from member companies to help PCRP engage with government and private agencies i.e. PHREN/ institutions/ hospitals/vendors/ suppliers in formulating mitigation plans.

**Please complete this survey by 20 March 2020:**

https://forms.gle/2RY6bqVpWgRz2jUf7

**Data from this survey will provide an overall picture of impact of the COVID-19 Emergency and corresponding government measures to clinical trial delivery.**

## Visit this folder for these references: PCRP COVID-19 Community

| Agency | Information |
|---|---|
| Philippine Government | • Proclamation No 922 s 2020 declaring a State of Public Health Emergency throughout the Philippines, 08 Mar 2020<br>• Memorandum from the Executive Secretary re the imposition of an Enhanced Community Quarantine and the Stringent Social Distancing Measures over the entire Luzon from 17 Mar to 13 April, dated 16 March 2020<br>• Proclamation No 929 s 2020 declaring a State of Calamity throughout the Philippines for a period of 6 months unless earlier lifted or extended as the circumstances may warrant, dated 18 March 2020 |
| PFDA | Letter to Clinical Trial Industry, dated 17 March 2020 informing that all clinical trial applications will be accepted but processing is on hold until further notice. All other submissions will be processed but with delays. |
| OMB | Guidelines during ECQ for application, clearance/permit for release, licenses with 30-day extended expiration and contact details for inquiries. |