PCRP
Philippine Clinical Research Professionals Inc.

COVID-19 CONTINGENCY GUIDANCE

DEAR PCRP MEMBERS,

We are pleased to send you the **Covid-19 Contingency Guidance ver 31 Mar 2020**. This version now includes a more detailed guidance than the 18 March 2020 version. Please note that the guidance comes with a powerpoint presentation that summarizes key points. This guidance was shared with PHREN and PFDA.

We encourage questions from our members. To do so please use the link below. A webinar or drop-in-call is scheduled at 10AM and at 2PM on Friday, April 3, 2020 for your convenience. The link will be sent shortly.

To keep abreast with what is happening at the P-FDA, IRBs and Institutions, please go to our PCRP Covid-19 Community Google Drive.

Clinical Trial Questions During COVID-19 Emergency
Let us know your questions related to the COVID-19 Guidance, PFDA, BOQ, etc.
Click here: https://forms.gle/3aFye2p3U29RWgzJ9

PCRP COVID-19 Community Google Drive
Click on the link below to access memos from government agencies, P-FDA, IRBs, and Institutions, industry guidance and partner vendors.
https://drive.google.com/drive/folders/1iZd9yo_gNcHlmRb5_1XJ9AIKQIsh_c0?usp=sharing

Thank you for your unwavering support to PCRP. We hope that you and your families are safe.

Sincerely Yours,

Rodmar C. Pulido

Rodmar Pulido
PCRP President

Released on 01 April 2020.

PCRP

Philippine Clinical Research Professionals Inc.

COVID-19 Contingency Guidance from PCRP ver 31 Mar 2020

Prepared by

Philippine Clinical Research Professional, Inc. (PCRP)

Philippines is under an Enhanced-Community Quarantine (ECQ) (lockdown) from 17 March to 13 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
- Recruitment Interruption
- 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.

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 has ongoing consultations with government and private agencies – Philippine Health Research Network (PHREN), institutions/hospitals, vendors and suppliers to manage the risks on Trial Subjects' safety, access to data and overall clinical trial conduct.

To safeguard the safety of clinical Trial Subjects, these contingencies and mitigations may be implemented immediately,
upon engagement and agreement of the Investigator and the Sponsor.

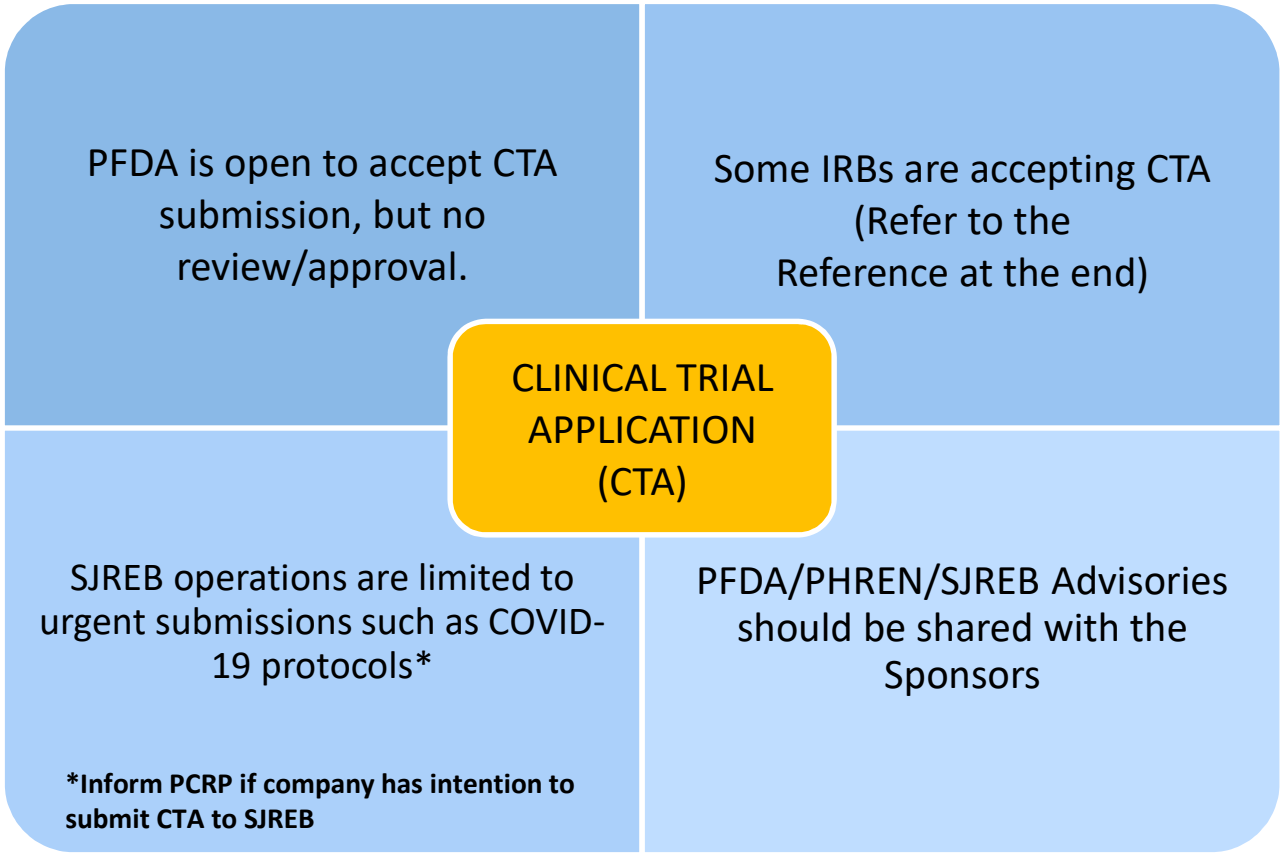
Inform PFDA and REC as soon as possible.

Good Clinical Practice must be followed at all times, including seeking consent from patient for any procedures and/or provisions.

*To further help you on this guidance document, please refer to the manual entitled "**PCRP Guidance Document for the Conduct of Clinical Trials during COVID-19 version 31 March 2020**"*

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

CONTINGENCY FOR STUDIES ON START-UP/MAINTENANCE PHASE



CONTINGENCY ON STUDIES FOR SIV*

*Site Initiation Visit

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 ONGOING STUDIES*

*recruitment, follow-up

Hold Recruitment

- Discuss with PI & inform relevant offices (REC, FDA, hospital departments)

Enrolled Patients

- PI should inform active patients about changes in study that impact them and allow them to make informed decision
- Have a sponsor approved plan for critical protocol assessment or safety monitoring, continuing access to IP, even study discontinuation relevant to trial participant safety

CONTINGENCY FOR ONSITE MONITORING VISITS

Postpone Onsite Visits

- Discuss with your PI alternatives to onsite visits
- Discuss with the PI the changes to the monitoring plan

Remote monitoring

- Where possible, define critical protocol activities to focus
- Document deviations in the monitoring plan/ remote monitoring visit report
- Communicate closely with the project team & site staff
- Review company guidance and take relevant training (eg checklist)

ASSESS IMPACT PER STUDY

Applicable to ALL Studies

- Remote contact for all Trial Subjects must be conducted
- Heighten the vigilance on adverse events
- Be aware on possible Trial Subjects with COVID-19 exposure

VISITS IMPACTED BY ECQ

- Trial Subject visits will have deviations from study protocol
- Subject visits with laboratory or any clinical investigations/assessments
- Subject visits requiring Investigational Product dosing in a health care facility
- Subject visits that require take home medications may opt for Direct-to-Home Investigational Product re-supply

All Studies : Remote contact for all Trial Subjects must be conducted

- Are Trial Subjects “all accounted for”?
- Are Trial Subjects willing to continue in the trial?
- Need to on-board Trial Subjects on the changes to visit plan (i.e safety from COVID-19)

All Studies : Heighten AE Vigilance

- Remind Trial Subjects of quarantine protocol
- Increase awareness on new AEs and trends in AEs reported by Trial Subjects
- Consult Medical Monitor when needed
- Document in source, update CRF timely

All Studies : Investigate Trials Subjects with COVID-19 Infection

- Reports of COVID-19 infected Trial Subject must be investigated - know where Trial Subject is managed (eg hospital, home quarantine)
- Immediately report to Medical Monitor (Sponsor) and DOH Surveillance Team as per local policy
- Monitor Trial Subject status regularly

Protocol visit deviations during ECQ

- If no impact on safety, delay Trial Subject visit
- Get Sponsor guidance on critical efficacy and safety assessments feasible to do remotely
- Identify the protocol deviations needing reporting

Safety/Clinical investigations and assessments that cannot be delayed

- Critical safety and/or efficacy assessments cannot be conducted remotely and/or cannot be delayed or postponed, assess if:
  - Trial site is accessible and safe for subjects to visit
  - A different investigational site within the same study is available
  - A local lab/health facility near patient location as alternative option
- Guidance for management of safety laboratory/ clinical investigations done outside
  - Do qualification, whenever possible eg ask lab/facility certifications, lab normal ranges
  - Access to results
  - Management of potential AEs
- Medical decision on Trial Subject disposition in the trial (eg withdraw subject?)
- Subjects must be provided with Personal Protective Equipment (PPE) and advised with other safety precautions as required by the health facility

IP Dosing in a Healthcare Facility

- IP dosing needs to be done in a health care facility and cannot be delayed or postponed, consider options:
    - Dose IP at trial site, if accessible and safe for Trial Subject
    - Dose IP at another investigational site within the same study for multicenter trials, with the Investigator to his/her own respective Trial Subject
    - Dose IP at another healthcare facility with no COVID-19 patients
- Involvement of alternate healthcare facility to serve as satellite site and/or involvement of alternate health care professional who will be involved with Trial Subject must follow site and staff qualification requirements and must obtain approvals by REC and PFDA
- Protocol must follow Interim health care professionals to provide the dosing must be qualified and trained on the protocol-IP administration
- Subjects must be provided with Personal Protective Equipment (PPE) and other safety precautions as required by the healthcare facility

Direct-to-Home IP Re-Supply to Trial Subject

- Applicable for studies that require take-home medications to Trial Subjects
- Direct to home arrangement must be agreed upon by PI and Trial Subject
- Data Privacy compliance of sponsor, logistics provider and patient is required
- Inform REC

Trial Subject Safety Considerations

- Quarantine pass, medical appointment letter
- PPE, mask, goggles, gloves (whichever is required)
- Fit to travel assessment of Trial Subject in relation to COVID-19 precaution
- Subject ID card
- Safety precautions even after ECQ

Visit this folder for references: **PCRP COVID-19 Community**

(examples of files/documents below)

Agency	Information
Philippine National Government	• Proclamation No 922 s 2020 declaring a State of Public Health Emergency throughout the Philippines, 08 Mar 2020 • 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 • 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.

SUMMARY OF CHANGES from Version 19 March 2020

Version 19 Mar 2020	Changes
Slide 2	Date of ECQ period changed from (15 Mar to 14 April) to (17 Mar to 13 April) 'Recruitment hold' changed to 'interruption'
Slide 4	Added additional column (shaded green)
Slide 5, 10-18	New additional slides
Slide 7	'Active recruitment' changed to 'ongoing studies' Added categories for 'hold recruitment' and 'enrolled subjects' Added additional contingencies
Slide 8	Added 'monitoring' to 'monitoring visit' in the Header Added and/or re-arranged contingencies
Slide 9	Revised entire slide to introduce mitigations