CALL FOR PROPOSALS

Technical Assistance to Strengthen Capacity of DOH in Monitoring and Analyzing Safety Data from Sponsored Clinical Trials

World Health Organization
Representative Office for the Philippines

1. Summary

As the Department of Health (DOH) gears up to take part in global and local scientific researches on therapeutics and vaccines for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), DOH must obtain capacity to assume the role and responsibilities of a clinical trial sponsor or co-sponsor. In support of this, the World Health Organization (WHO) Philippines is searching for an institutional or individual partner to capacitate DOH in monitoring and analyzing safety data generated from sponsored clinical trials. The proposals are due by 08 July 2021.

Background

The SARS-CoV-2 or COVID-19 pandemic continues to rapidly evolve, affecting health and economies in great proportion. Leaders and public health experts worldwide have stressed that the pandemic likely will not end until there is an effective therapeutics and vaccine. A global effort is underway to repurpose potential therapeutics and develop effective vaccines to counter the new and highly infectious COVID-19. The development and discovery of these tools could help reduce the infectivity, severity and duration of COVID-19 illness in the interim.

Clinical trials are crucial indicators of whether a vaccine or a pharmaceutical product is effective and safe. Recognizing the need for vaccines and therapeutics, researchers around the globe are accelerating the clinical trial process. Further, country support and participation in global randomized trials complement these efforts.

The government and public health agency play critical roles in vaccine and therapeutics research. In the Philippines, the Department of Health (DOH) co-sponsors and ensures that COVID-19 clinical trials are conducted in accordance to ethical principles, consistent with Good Clinical Practice (GCP) and the applicable regulatory requirements. Accelerating the clinical trials will require a more fortified system of monitoring. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society. In order to ensure safety of clinical trial participants, the trial sponsor must have the capacity to assess and analyze safety data and critical efficacy endpoints in regular intervals as the clinical trial progresses. Sponsors are expected to confidently make sound recommendations whether to continue, modify, or terminate a sponsored trial.

2. Timeline

The implementation timeline for the project is from **15 July 2021 to 14 September 2021**.

3. Place of Assignment

Manila, Philippines

4. Scope of Work

Under the supervision and guidance of the Health Systems Team Coordinator of WHO Philippines Country Office, the APW will work together with DOH Health Policy Development and Planning Bureau in strengthening the capacity of the DOH Data Safety Monitoring Committee (DSMC).

Output 1: Improving DSMC Operational System

Deliverable 1.1: Review DOH Charter for DSMC and SOPs, and provide recommendations for improvement, as necessary
Deliverable 1.2: Recommend approval of Charter and SOPs

Output 2: Strengthening Capacity of DSMC

Deliverable 2.1: Capacitate DOH DSMC in the analysis of safety data and in the crafting of sound recommendations and technical advice to the DOH Steering Committee
Deliverable 2.2: Conduct other capacity building activities based on training needs of DSMC

Output 3: Workplan and Reports

Deliverable 3.1: Submission of Workplan and inception report
Deliverable 3.2: Submission of progress report and minutes of meetings
Deliverable 3.3: Submission of final documentation

5. Qualifications

The individual contractual partner or institution's members must fulfil the following qualifications:

Education and Certifications

- Master's degree or higher education in medicine or biomedicine, clinical epidemiology or equivalent
- Certifications or credentials in infectious diseases, pharmacology, toxicology, vaccines, research, biostatistics, statistical analysis, clinical trials, regulations, good clinical practice, data safety analysis and monitoring

Work Experience

- At least 7 years of experience in data safety monitoring in local and international multi-center clinical trials on therapeutics and vaccines
- Recognized and with good standing among peers, institutions and network of clinical researchers locally and/or internationally

Technical skills and knowledge:

- Highly skilled in safeguarding the interest of study participants, preserving the study credibility and facilitating the availability of timely and reliable findings
- Planning and monitoring of clinical study, progress and reports; comprehensive analysis of safety data; preparation of safety reports and recommendations

Language

- Good English communication (writing and speaking) skills.

In addition, the individual/institution and its members shall not be involved, in any form, in drugs, arms dealing, alcohol industry, or human trafficking.

6. Contract Time

The work to be done under this contract is to Strengthen Capacity of DOH in Monitoring and Analyzing Safety Data from Sponsored Clinical Trials as set out in the Terms of Reference. The contract will be completed in not more than 3 months from the commencement of the Work, or otherwise as agreed in writing among the Owner and the Contractor. The work shall be done in strict compliance with the Contract, Specifications, Schedules, and all other Contract documents and all Instructions. Failure to do so shall be at the Contractor's risk and account. Submission of Bid by the Contractor shall constitute acknowledgement by the Contractor that it is aware of and concurs with all the requirements or conditions incorporated in the Call for Proposal and the other documents.

As time is an essential element of this Contract, for failure to complete all work within the stipulated as set out in the Terms of Reference, the Owner shall charge the Contractor liquidated damages. This shall be in the amount the sum of 0.5% of the total contract amount per day (Saturdays, Sundays and holidays are included) but not to exceed on total 10% (ten percent) of the contract amount. These liquidated damages shall be for the added cost incurred by the Owner for such delay and for the inconvenience caused to the users of the Work. It is understood that this is not a penalty but a fixed sum representing the liquidated damages for each calendar day of the delay. Delay shall be counted from the agreed completion date, considering further time extensions approved by the Owner, to the date of completion of work.

7. Other Requirements

N/A

8. Submission Requirements

Interested institutions and/or individuals should submit electronic copies of the following:

- Cover letter
- Proposal with financial details and proposed timeline
- Company profile and qualifications of team members (if institution) or curriculum vitae (if individual)

Address all cover letters and proposals to:
Dr Rabindra Abeyasinghe
WHO Representative to the Philippines
Ground Floor, Building 3, Department of Health San Lazaro Compound
Rizal Avenue, Sta Cruz, Manila

Please submit the electronic copy of the cover letters and proposals with the title **Technical Assistance to Strengthen Capacity of DOH in Monitoring and Analyzing Safety Data from Sponsored Clinical Trials** to Mrs Ying Chen (cheny@who.int) and wpphlwr@who.int
Only shortlisted applicants will be contacted by WHO Philippines.

Deadline of submission of application is on **08 July 2021**.