
EDITORIAL

“For after every storm, the sun will always shine”. This quote perhaps perfectly reflects our current situation. Throughout May to July, our country was hit by the merciless second wave of COVID-19 pandemic and never before we could ever imagine the chaotic results of the uncontrolled COVID-19 widespread infection that brought us to the brink of a healthcare system collapse, resulting in a massive loss of so many lives, including those of our beloved colleagues. The lives lost could never be regained, but the memories should always be honoured forever. This edition of *Ophthalmologica Indonesiana* is specially dedicated to our teachers, colleagues, and friends whose lives were lost during this pandemic.

My utmost appreciation for the team of *Ophthalmologica Indonesiana* who despite all odds is able to publish this edition punctually as scheduled, and also for the enthusiasm from the authors from which we have received numerous fascinating manuscripts, including some exceptional case reports. All of submitted and published papers will help us greatly for improving, updating, and keeping up with the current knowledge in ophthalmology, essential for the best approach in daily clinical practice.

COVID-19 pandemic has abruptly changed our lives. Changes that dramatically occurs not only to our daily lives, but also to every aspect of our medical practice, our professional lives as clinicians, researchers, or academicians. Ophthalmological research trials conduct has also been majorly disrupted. Aside from answering the scientific questions themselves, we will also need to address the questions on how to safely conduct scientific research during this pandemic while preserving good methodology. How can we continue on carrying out research while ensuring the safety of the participants and researchers above all else? Temporary relaxation of trial protocols might be needed to address those questions, while maintaining adherence to the established regulations and guidelines.

During the earlier months of COVID—19 pandemic, most prospective studies conducted in the United States, especially clinical trials, was suspended to (1) ensure the safety of both the participant and researcher, to (2) focus most of the scientific research towards the pandemic itself, and to (3) adapt new measures to deal with the situation. Other countries, however, have chosen the alternatives to continue on with their studies, while altering some steps along the way, such as a more flexible follow-up time, employing the use of contactless devices for the patients, or through telemedicine, all of which would be halted should the pandemic went uncontrollably

As time goes by, the COVID-19 pandemic has slowly entered an era of a “new normal” and life must go on, including for clinical development and trials. The conduct of any trial during these times must strictly follow regional laws, as well as hospital regulations and restrictive policies for the prevention and control of COVID-19. The safety of both trial participants and researchers has to be of the highest priority. In order to accommodate these measures, trial team must prepare for alternative development plans that might accommodate the necessary changes to ensure the utmost safety, accordingly. These plans include the possibility of protocol deviations, flexible working hours with potential additional work time, visit restrictions, disruption in supply chains, and new data management provisions (including the use of telemedicine to capture follow up data); all of which, while contribute to additional costs and labour, are also needed to ensure key strategies necessary for a successful and safe research environment.

The ongoing mutation of this virus has caused numerous lockdowns and social restrictions in most part of the countries, creating challenges for patients and trial participants to mobilize to- and from- hospitals regularly. This unique situation has created a new challenge for researchers, especially for those whose clinical trials or prospective studies design mandates regular follow up from the participants, while creating a possibility of larger participant drop-out from the trial. Few has been written about the methods, risks, challenges, and opportunities faced by clinical trials during these times, and what has is almost entirely focused on the pandemic itself. A shift of focus to minimize exclusion number and carry out ethical research must also be carried out to ensure the success of the trial itself. Other measures that might be considered in conducting clinical trials during these times include:

1. Choosing the appropriate study topics, including tailored inclusion criteria
2. Minimalizing exclusion criteria. The possibility of exclusion due to follow-up failure might increase due local restrictive measures, economical constraint, participant's hesitancy to visit hospitals, and health concerns. This step needs to be taken to limit the number of exclusions from the beginning, and to include as many as potential participant in the early phases of the trials.
3. Home visit for follow-up, if all parties' safety can be ensured, could be considered to minimize exclusion and dropouts.
4. Utilizing telemedicine and digital system for follow up might also help in minimizing drop out numbers, especially if special restrictive measures is employed by the government. A solid digital data collection will then need to be established to facilitate these measures.

Any difficulties and changes in trial protocol due to COVID-19 situation must be well recorded. This includes disrupted protocol due to lockdown or local restriction (inaccessibility for patients to visit hospitals and trial centres), technical difficulties due to transportation restriction, or other protocol deviation. These potential protocol deviations must also be communicated with the ethical committee prior to and during trial for special consideration.

COVID-19 pandemic has proved by far to be the most challenging situation faced by the medical field in this century. All aspects of lives are affected, including the research field. It is indeed a difficult time for researchers to conduct trials, however, clinical development through scientific research will always be crucial for medical field. Research and trials in medical field must be continued, while employing multiple strategies to deal with the unique situation. Despite the challenges faced by clinical trials in these unprecedented times, it is not impossible for us to create good, innovative, and ground-breaking reports that will contribute greatly to ophthalmology advancement in Indonesia. I believe there is still a high level of excitement from fellow ophthalmologists all over the country in the research field, as we are never short of submission of extraordinary studies and case reports. I am thankful for the enthusiasm and will always encourage all of you to keep on creating astonishing work. Stay safe and healthy.

Warmest regards,

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