



Date: March 30, 2020
Concerning: **Instruction for study sites participating in a HOVON study during COVID-19**

Dear National Coordinator of HOVON,

Keep HOVON informed

Due to national COVID-19 protective measures, Sites that participate in HOVON studies may encounter difficulties in the performance of the studies. Superfluously, HOVON hereby ensures all sites that the current situation is considered a force majeure situation.

However, as outlined in the site agreements, parties have an obligation to inform each other on the circumstances surrounding the force majeure event. Moreover, as the sponsor of a study, it is of utmost importance for HOVON to be informed of the possibilities and impossibilities for sites to what extent and under which circumstances continuation of the clinical studies is feasible at the site.

Therefore, all sites are herewith requested to update HOVON of the continuation of the HOVON studies at the site and with respect to these studies, how the restrictions imposed by national health security measures relating to COVID-19 affect the site's performance. For example, HOVON is interested in potential discontinuation of recruitment, measures to continue the study at a safely manner, alternatives for hospital visits and distribution of study medication to the subjects and expected delays in executing the required investigations within the study. Of course any protocol deviations require to be reported in the patient file.

National coordinating centers are requested to collect such information on a regular bases from the participating sites contracted by them and forward the information to HOVON. Mention in the heading the name of the hospital and structure all information including the above and any issue affecting the performance per HOVON study number involved.

The information is important for HOVON to monitor the studies and to determine whether studies are continued in safely and scientifically sound manner and potentially to response to requests of authorities and study funders.

HOVON

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This situation is new to all of us, and HOVON may ask you to provide additional information if needed. However, we anticipate to keep the workload for the sites at a minimum.

Distribution of study medication

Some sites posed questions relating to the distribution of study medication. HOVON advises all sites to as much as possible distribute study medication aligned with medication administered for normal patient care. Family members may be able to collect study medication at the site. All distribution should be in compliance with applicable law.

As you may be aware, HOVON studies are performed with limited financial resources and it is only feasible for HOVON to assess whether financial support can be made available for study medication distribution after the protective measures are lifted in all countries. We will keep all sites updated on the possibilities.

Questions

If you have any questions relating to the studies your site is participating in, please contact the HOVON Data Center at HDC@erasmusmc.nl or the trial manager of the study.

Kind regards,

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