

The Health and Youth Care Inspectorate has published the following message on its website (in Dutch):

Consequences of the COVID-19 pandemic on the conduct of GLP safety studies.

The COVID-19 pandemic has forced governments to issue strict limitations in social and professional contacts. These restrictions may also interfere with normal daily routine and working practices in test facilities conducting GLP safety studies. The measures that have to be taken may also have an impact on the GLP status of studies. Deviations from normal operating procedures (including SOPs) and study plans due to this situation should be documented in full detail and the effect on the GLP status of studies should be assessed. If applicable, the study director should issue study plan amendments and/or describe deviations from the study plan in the final study report. Any non-GLP compliant study phase should be identified in the study director's compliance statement in the final study report. The impact of the imposed restrictions, if any, on other test facility operations including non-study specific activities and QA inspections should also be assessed and be included in the evaluation of the GLP status of studies.

The inspectorate has suspended all inspection activities for the time being. Depending on the development of the situation in the coming weeks the inspectorate will decide when and how inspections will be initiated again. The inspectorate will assess the measures taken at test facilities during the lock-down period and evaluate their potential impact on the GLP status during routine inspections.

For more information or any questions, please contact the inspectorate by e-mail: glp@igj.nl.