



International Breast Cancer Study Group

IBCSG

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Coordinating Center

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Dear All,

Restrictions and stringent measures implemented worldwide to contain the spread of the COVID-19 virus are affecting the conduct of clinical trials.

We are aware that this situation is very challenging for hospitals that participate in our clinical trials, especially as oncology patients are particularly at risk in the current situation. Therefore, the safety of our patients has the highest priority!

The investigator and treating physician should decide what is best for the patient. These exceptional circumstances have led many institutions and national health authorities to issue guidance for the conduct of clinical trials specific to the local situation. These recommendations have the overriding goal to protect the safety of the patients. We are aware that this will result in protocol and standard operating procedure deviations, including e.g. failure to comply with monitoring and audit visits. Please make sure we are informed and these deviations are clearly documented in the patient's chart and in the database.

In addition, as the COVID19 pandemic seriously affects hospital capacities and patient's possibilities to safely travel to the hospital. In the interest of the patients' safety, we ask you to consider each new patient enrollment carefully.

We strongly recommend that at the moment randomization/enrollment of patients is only considered if the travels for protocol-specified visits can be ensured and the hospital is expected to have the capacities to perform all the visits and assessments according to protocol.

Please be assured that all our activities and services continue to be maintained.

For advice on how to handle specific situations, please do not hesitate to contact the responsible trial coordinator via the trial-specific email address.

We thank you very much.

Be safe and stay healthy

Kind regards,

Anita Hiltbrunner
IBCSG Director