Letter of suspension regarding the FLORA trial (NCT03058900)

Dear all,

Due to the latest development in the official response to the COVID-19 outbreak which includes the suspension of research activities at public hospitals imposed by the Danish government, Odense University Hospital do not allow clinical visits unless they are reasoned by “acute illness”. We are forced to suspend all planned clinical FLORA trial visits and research tissue sampling as of today, 15th of March 2020, and until further notice.

Hence, FLORA visits will be modified in accordance with the current practice for non-acute ambulant activities at Odense University Hospital. Consequently, FLORA patients will be contacted by phone at the time of the planned visits. Here, the primary endpoint (treatment failure) will be discussed as shared decision making between the treating rheumatologist and the patient. Only patients who present with active disease symptoms or in case of adverse events will be asked to attend a clinical visit that will be conducted by the trial rheumatologist.

Patients will be asked to fulfill patient-reported outcomes (e.g., HAQ-DI) directly into the REDCap database via an email link at the pre-specified time points. No collection of biobank samples will be conducted. Blood tests for MTX toxicity will be performed as planned.

When the situation improves and the official recommendations allows, we will resume the conduct of the remaining trial visits in accordance with the study protocol.

On behalf of the FLORA trial steering committee,

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