

NCA notification requirements (24 Mar 2020):

Temporary halt of recruitment: In case of temporary halt of recruitment due to COVID-19 notification shall be sufficient and the restart of recruitment is not considered as a substantial amendment either. Notifications can be made within one letter even in case of more clinical studies.

Urgen Safety Measures: When substantial modifications of the study are required in order to ensure the patient's continued participation, sponsor may do so as an "urgent safety measure" (USM). The change will take effect immediately. The urgent safety measure should be sent to the authority and the amendment should be subsequently, officially authorized in accordance with the usual procedure.

Study on-hold or termination: If the continuation of the study is not possible at the investigational site any more, and the relocation of the site also meets with difficulties, subjects should be informed in the simplest way, via telephone. Similarly, to telephone visits, this must be documented as well, and – considering the risk-benefit assessment – decision should be made whether the sponsor puts the study on hold or terminates it. Our Institute should be informed about this decision subsequently giving the reasons and the exact time points.

PI change due to COVID19: In every case, when the principal investigators cannot complete their tasks due to protective measures or illnesses, the sub-investigator previously delegated to the study can take over their role. This also needs to be documented, and our Institute should be informed about the change subsequently, when the situation has normalized.

Site moves: If any site moves to another settlement of the institute, or other health care institute due to the evolved crisis, and there the study is continued, the Institute only needs to be informed subsequently giving the exact dates of the address change.

Study subject care in a location not approved previously: There is also an opportunity for the investigator to move the patient care to a private surgery that has not been marked as a satellite-site before, but the Institute and the Ethics Committee needs to be informed, and subsequently it needs to be submitted as an amendment.

IMP DTP: In cases like this the responsibility remains with PI. Transportation of IMPs from the site/institution pharmacy is preferred. The person who performs the transportation of IMPs must know the guidelines with regard of IMP handling. Special storage conditions must be documented all the time, but there is no need to inform National Competent Authority about this change.