Joint guidance of Swissmedic and swissethics on the conduct of clinical trials during COVID-19 pandemic

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CRAs with limited or no access at all to hospitals and limited SDV possibilities:

- Reduce monitoring to the necessary minimum or, if appropriate, omit completely.
- Check remotely in case of SUSAR or crucial patient safety issues.
- "Remotely monitoring" clearly excludes the sharing of electronic patient files via computer screens by using Zoom, Skype or other comparable tools. There is no legal basis for this procedure and it is not acceptable under the current conditions. In the future, this possibility might be given with decentralized clinical trials.
- Solve questions on SUSAR and, for example, patient safety issues over telephone whenever possible.
- Adapt monitoring plans accordingly. Send them to EC for silent acknowledgement. Delayed submission is acceptable, there will be no formal approval.
- Clearly document what is done outside the usual process.

Reporting to ECs and Swissmedic:

- Bulk submissions for several studies of one company are accepted. One single information letter is sufficient. Upload it to all concerned studies in BASEC (only for submissions to ECs. It is recommended to contact the lead ethics committee before doing so.).
- Do not overflow the authorities with individual questions.
- On hold recruitment does NOT have to be submitted if already enrolled patients continue to be treated in the respective clinical trial.
- If the sponsor decides to temporarily interrupt or to definitely discontinue a clinical trial, the ethics committee and Swissmedic must be notified within 15 days, as per ClinO art 38 abs. 2 and abs. 5 respectively.
- Please keep EC channels open for more important items, for the moment being.
- Stay informed and regularly check what swissethics publish on their COVID-19 dedicated webpage. Check the webpage, also for information regarding HRO research projects.

IMP and study medication logistics:

- Sending medication directly from the sponsor to the patients at home is not compliant to GCP. Aspects like compliance issues or storage conditions are not controllable anymore and thus unsafe for the patients.

- Life-threatening diseases may be an exception which has to be carefully assessed. In any case, ECs and if applicable Swissmedic have to be informed in advance.

Assessments by family doctor or other hospital:

- This is theoretically possible if the patient refuses to travel to the site, but depends on the investigator's agreement with the doctor concerned. It should be limited to simple procedures and thus it has to be considered whether this makes sense at all.

Patient with symptomatic SARS-CoV-2 infection:

- Report as **SAE**.

Exceptional expenses of patients:

- Example: Patient does not want to travel by train, but the travel distance by taxi between the patient's home and the site is for example 100 km. Reimbursement of such high taxi costs is accepted and does not need special approval from ECs.

Questions to EC and Swissmedic:

- Please reduce to the most urging for the time being.
- Normal channels for questions are open at both Swissmedic and ECs.

Studies on COVID-19 therapy and vaccination:

- Align early-on with Swissmedic and ECs, for example on PIIC. Approval will be prioritized and given in very short time.

Inspections:

- Currently on hold.
- They will be resumed again after clarification of the COVID-19 issue.
- In this respect: Swissmedic strongly recommends to well document whatever you do now in the context of the current exceptional state.

The guidance document has been issued as the result of the teleconference between Swissmedic, swissethics and Interpharma, held on March 18, 2020, 3 p.m.