Joined guidance Swissmedic – swissethics on the conduct of clinical trials during COVID-19 Pandemic

Limited or no access at all of CRAs to hospitals / limited SDV possibilities:

- Cut down monitoring to the least possible essential or more or less completely
- Check remotely in case of SUSAR or crucial patient safety issues only
- "Remotely monitoring" clearly excludes sharing of the computer screens into the electronic patient file by using Zoom, Skype or other comparable tools.
- There is no legal basis for this and may not be done so, is not acceptable under current conditions. It will though come in the future with decentralized clinical trials.
- Clarification on questions to SUSARs and such items on patient safety, for example: strive to do by phone.
- Adapt monitoring plans accordingly. Send them to EC for silent acknowledgement. Delayed submission is acceptable, there will be no formal approval.
- Document very well whatever you do out of the "normal" process.

Reporting to ECs and Swissmedic:

- Bulk submissions for several studies of a company are accepted. One single letter informing only, upload it into 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.
- Hold on 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 definitively discontinue a clinical trial this must be notified to the ethics committee and to Swissmedic 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
- Have a look at what Swissethics publishes on their homepage.
- Have a look at the News on the swissethics homepage, also for information regarding HRO research projects.

IMP / Study Medication logistics:

- Sending medication home to the patient actually is not an option compliant to GCP. Safety of patients, compliance issues, storage conditions, all of this is not controllable anymore and thus unsafe for the patients.
- Life-threatening disease may be an exception which has to carefully assessed and best discussed and ECs /Swissmedic have to be informed ahead of you intend to do so.

Assessments by family doctor or other hospital:

- Theoretically possible, if the patient refuses to travel to site, but depends a lot on what the Investigator agrees with the other doctor concerned. Rather limited to simple procedures and thus it has to be considered if this makes sense at all.

Patient with Covid-19 infection?

- Report as **SAE**.

Exceptional expenses of patients?

- Example: Patient does not want train, travel 100Km with taxi. Reimbursement of such high taxi costs is accepted and does need no special approval from ECs.

Questions to EC / Swissmedic?

- Please restrict to the most necessary for the time being.
- Normal channels for questions are open at both Swissmedic and ECs.
- Kind request to inform Clinical Research Working Group (CRWG) president Simon Rotzler, if something of general interest is clarified so that we can share it and prevent someone else asking the same thing again.

Studies on Covid-19 therapy / vaccination?

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

Inspections?

- Currently on hold.
- There will resume again after clarification of the Covid-10 issue.
- Thus once again: strong recommendation from Swissmedic do well document whatever you do now in the context of the current exceptional state

The guidance document was issued from the result of the teleconference Swissmedic – swissethics – Interpharma held on March 18, 2020, 3pm.