

The role of swissethics and ethics committees during the COVID-19 pandemic

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swissethics has provided information and developed resources related to the COVID-19 pandemic on the "COVID-19" section of its website, which includes the following:

- a summary report published on 1 July 2020 outlining the work carried out by the seven Swiss ethics committees (ECs) from January to the end of May 2020 DE FR (see Box 1)
- regularly updated online lists of <u>submitted and approved applications</u> for clinical trials and projects on COVID-19 in Switzerland EN (see Box 2)
- a guidance document developed in collaboration with Swissmedic entitled <u>Joint Guidance of Swissmedic and swissethics on the Management of Clinical Trials with Medicinal Drug Products in Switzerland during the COVID-19 Pandemic.</u> This document contains specific guidance on risk assessment, the distribution of study medication, monitoring, study visits, informed consent procedures, safety reporting, protocol deviations, the resumption of clinical trial activities following the COVID-19 pandemic, and other relevant topics. This joint guidance is regularly updated; version 2.4 was published on 17 December 2020

• a list of links to relevant Swiss and international organisations and a wide variety of guidance documents related to COVID-19.

Box 1: swissethics report from 1 July 2020

swissethics published a report on 1 July 2020 summarising the most important issues for Swiss ECs in the first months of the COVID-19 pandemic until the end of May (DE, FR). The report shows how ECs supported researchers with extremely short processing times despite receiving significantly more research applications than usual. In addition, ethical standards are discussed in the report, particularly with regard to informed consent. It will be interesting to receive an updated analysis and figures for the whole period of the pandemic until now, including recommendations for measures that can be continued or adjusted after the pandemic and included in the revision of the Swiss Human Research Act (HRA).

Processing an unprecedented number of research project applications in record time

The summary report from swissethics also indicates that since the start of the pandemic in March 2020, Swiss ECs have experienced a large increase in the number of applications for research projects. Compared to 2019, project applications submitted to ECs in the months of March, April, and May 2020 increased by 57%, 94%, and 33% respectively. The urgency of the pandemic has increased the time pressure to process project applications. ECs have prioritised COVID-19 projects, and several ECs have even created special COVID-19 teams to handle these applications more expeditiously. Even while working remotely, ECs have been able to work extremely quickly. Between 1 January 2020 and 31 May 2020, the median processing time nationwide dropped significantly from 24 days (for pre-pandemic non-COVID-19 projects) to 6 days (for COVID-19-related projects). In terms of the type of request and categorisation, research projects involving people according to chapter 2 of the Human Research Ordinance (HRO) and further use projects as defined in chapter 3 of the HRO have dramatically increased (they more than doubled in April 2020 compared to 2019). Clinical trials have also seen some increases – for example, with almost 40% more in April 2020 compared to the previous year. Despite this significant increase in volume and the time pressure facing ECs, ethical standards remain their utmost priority; swissethics affirms in its summary report that ECs have maintained the quality of the review process throughout the pandemic.

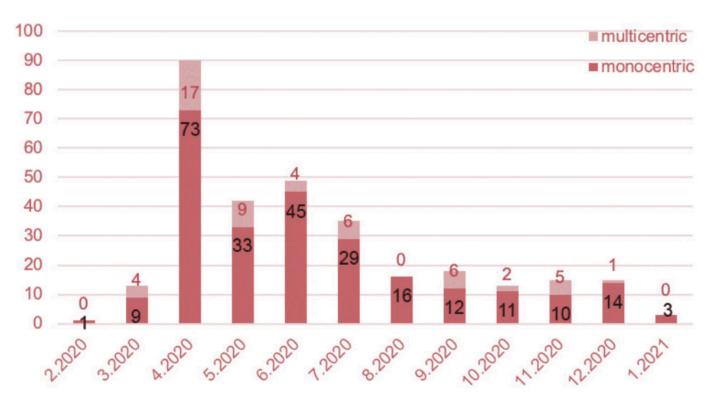
Improving coordination and using innovative consent solutions

Another challenge, especially at the beginning of the pandemic, was the lack of coordination between the researchers of many COVID-19 projects. Even though multicentre projects might have been more beneficial, many of the initial applications were for monocentric projects. To improve coordination, swissethics began publishing and regularly updating lists of submitted and approved applications for clinical trials and pro-jects on COVID-19 in Switzerland EN. As indicated in the summary report from swissethics, individual ECs also increased their local coordination efforts; the ethics committee in Vaud, for example, was able to reduce submitted applications by over 20%. Moreover, ECs have worked with hospitals to find quick and pragmatic solutions to the COVID- specific challenges they have been facing – for example, obtaining informed consent and general consent. Obtaining consent was especially difficult at the beginning of the pandemic, when many of the patients affected were very ill and their relatives were not allowed in hospitals. Innovative consent solutions, such as getting an electronic signature on a tablet instead of paper or obtaining consent via SMS, have been used.

Box 2: Evolution of the number of approved clinical trials on COVID-19

In order to facilitate national coordination, swissethics began publishing two lists of submitted and approved clinical trials and research projects on COVID-19 in Switzerland EN. These lists are updated weekly. Detailed information about clinical trials on COVID-19 can be obtained on the Swiss National Clinical Trials Portal (SNCTP). Figure 1 shows the evolution of the number of approved projects since the beginning of the pandemic. It can be seen that the majority of projects were approved during the first six months of the pandemic, and there were significantly more monocentric projects during the whole period. It is noteworthy that the second wave of the pandemic has not triggered a second wave of research projects.

Figure 1: Evolution of the number of approved clinical trials and research projects on COVID-19 in Switzerland since the beginning of the pandemic



Source: swissethics, Excel list of approved clinical trials and research projects on COVID-19 in Switzerland, extracted 11 Jan. 2021