SCTO PLATFORMS

COVID: 1–9 work practices and lessons learnt at one CTU

Authors: Madeleine Vollmer(1) and Claudia Becherer(1)
Affiliations: (1)Department of Clinical Research (DKF), University Hospital Basel
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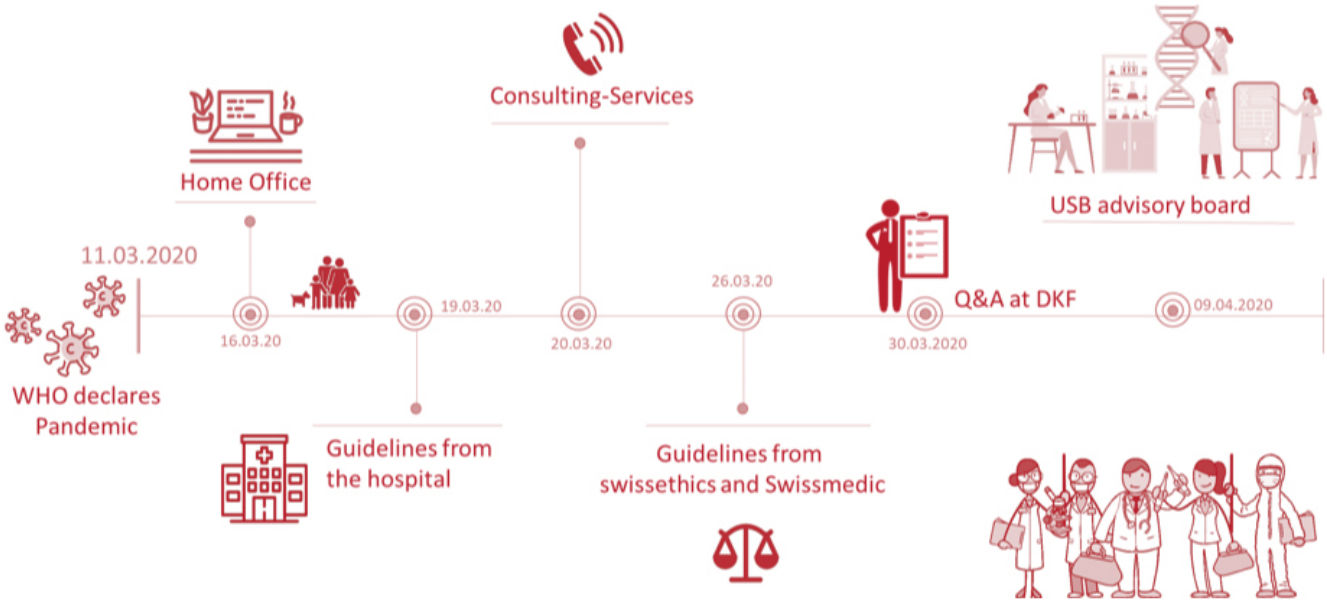
The pandemic hit us all much faster and to a larger extent than we could have imagined. We have had to find strategies for adapting quickly to the circumstances on both private and business levels. The Department of Clinical Research (DKF) at the University Hospital Basel (USB) has developed work practices for how to reconcile home office and work, how to handle frequently updated guidelines, and how to respond to questions from researchers about their clinical trials. In this article, we summarise nine DKF work practices and discuss lessons learnt during the corona crisis.



DKF’s corona crisis timeline

It was already clear to Churchill: Never waste a crisis.

On 11 March 2020, the World Health Organization (WHO) declared the coronavirus situation a global pandemic – a crisis caused by the SARS-CoV-2 virus. The coronavirus has shown us that we have to adapt to this new situation as fast as the virus spreads. Therefore, at the DKF – the Clinical Trial Unit (CTU) at the USB – we started finding solutions to stay on track both in our personal lives and in clinical research from mid-March until mid-May 2020.

1. From the office to home

If a virus is able to travel around the world and connect people (in a negative way), we too should be able to connect with our colleagues and clients around the world (in a positive way). Using all possible virtual communication tools (which were surprisingly user-friendly) helped us see and hear our colleagues and study teams almost as well as in real life. Short questions, long discussions, and important meetings all took place in a virtual world and with hardly any problems. However, each situation also has its disadvantages: not only were we working from home, but schools and kindergartens were also closed. This forced many of us to face another difficult situation: 60% of our employees are women who had to take care of their kids and dogs (and husbands). The period we worked from home was relatively short due to the low case numbers in Basel.

2. Consulting services

All possible DKF services rapidly switched from physical to virtual operations. Our statistics and consulting team shifted to virtual meetings, and we also offered a consulting hotline. This hotline was used frequently, with the requested services providing direct support. In addition, we provided a contact form on the DKF's website, and the required service answered the corresponding question in a timely manner. We received much positive feedback on these remote services, and users very much appreciated that services were still being provided. It was, however, more challenging for our consulting team to coordinate and communicate complex research issues that involved several parties. On the other hand, existing partnerships were deepened since communication took place for a short time but more frequently.

3. Guidelines from swissethics and Swissmedic

It goes without saying that this situation caused researchers to despair and raised more questions than we had answers to. We struggled with a variety of questions: if researchers could still include new patients, if COVID-19 had to be reported as a serious adverse event (SAE), if physical visits could be replaced by phone calls, and if people had to re-consent when additional data were acquired and if sponsors needed to report a study interruption. Although swissethics and Swissmedic provided useful guidelines in April to answer almost all of these questions, the guidelines were published quite late and did not cover all aspects of the issues. Revised and expanded versions were later published.

4. Questions and answers at the DKF

An example of a question not addressed by swissethics and Swissmedic was whether investigators were allowed to send medication to a patient's home. According to the guidelines, this was not allowed because the correct storage and temperature of the investigational medical product (IMP) could not be ensured. For

one of our clients, IMP storage was at room temperature, so we submitted our request and received approval to send medication to the patient's home. This is why the Regulatory Affairs team created a questions and answers (Q&A) list on our website that summarised and supplemented all questions that arose. We adapted the corresponding answers to the latest guidelines from all institutions, such as the Federal Office of Public Health, swissethics, Swissmedic, and the USB. This Q&A list advised researchers on how they could handle certain situations. The final responsibility, however, always remained in the hands of the sponsor.

5. Guidelines from the hospital

The USB provided additional institutional guidelines on how to handle (study) patients, remote working situations, and much more. Thus, not only did our Q&A list have be updated frequently, but our employees also had to react quite flexibly to new situations. However, in contrast to other hospitals, it was possible to continue specific studies. In order to organise the conduct of running studies at the USB, a specific advisory board for clinical research on COVID-19 was created. In addition, the DKF was involved in the USB's COVID-19 study task force, which coordinated all COVID-19-related studies according to their patient profile, research question, and/or data collection with the goal of using synergies.

6. USB advisory board

The clinical research advisory board decided which studies at the USB could be continued and which studies had to be interrupted. To help make this difficult decision, researchers had the opportunity to submit their application containing a justification for their study continuation (Did patients come for routine visits or extra study visits? Were patients undergoing important treatment for a life-threatening disease? etc.) and their protection concept. There were 116 studies that were evaluated, edited, and finally approved to be continued.

7. Situation for researchers

Contrary to our expectations, the number of study applications did not decrease in the lockdown phase, but rather increased. Not only were new trials about COVID-19 set up, but dusty studies that may have been lying in the drawer for a while and waiting to be brought out were also submitted. One had the impression that researchers had time for their research again – which may have been due the fact that some clinical areas were put on hold.

8. SCTO network

Fortunately, the CTU Basel was not alone in dealing with this situation. We could always rely on the Swiss Clinical Trial Organisation's (SCTO's) network to discuss regulatory questions, help us understand new guidelines, and give us tips on how to handle specific situations. However, we also realised that circumstances at the various CTUs differed. While the staff at most CTUs were still working from home and were not conducting any clinical studies, our CTU staff were already back in the office in May.

9. Lessons learnt

Ultimately, what did we learn? We learnt to react fast and adapt to changes. And that changes are not necessarily bad. We learnt how to do interdisciplinary work, we started using virtual desks, we gained time because of shorter commutes, we enjoyed working at home as we became more efficient and focused, and we had national meetings without needing to sit in a train. However, we also missed several things: seeing our colleagues in person, running to the next office for a quick question, not having to prepare our own lunch, or getting a signature in a minute. Did we waste the crisis? Not at all. Because here we are in March 2021,

back in home office (again) but fully operational.