11 March 2021 – one year of COVID-19: Reflecting on lessons learnt so far as we move towards the light at the end of the tunnel

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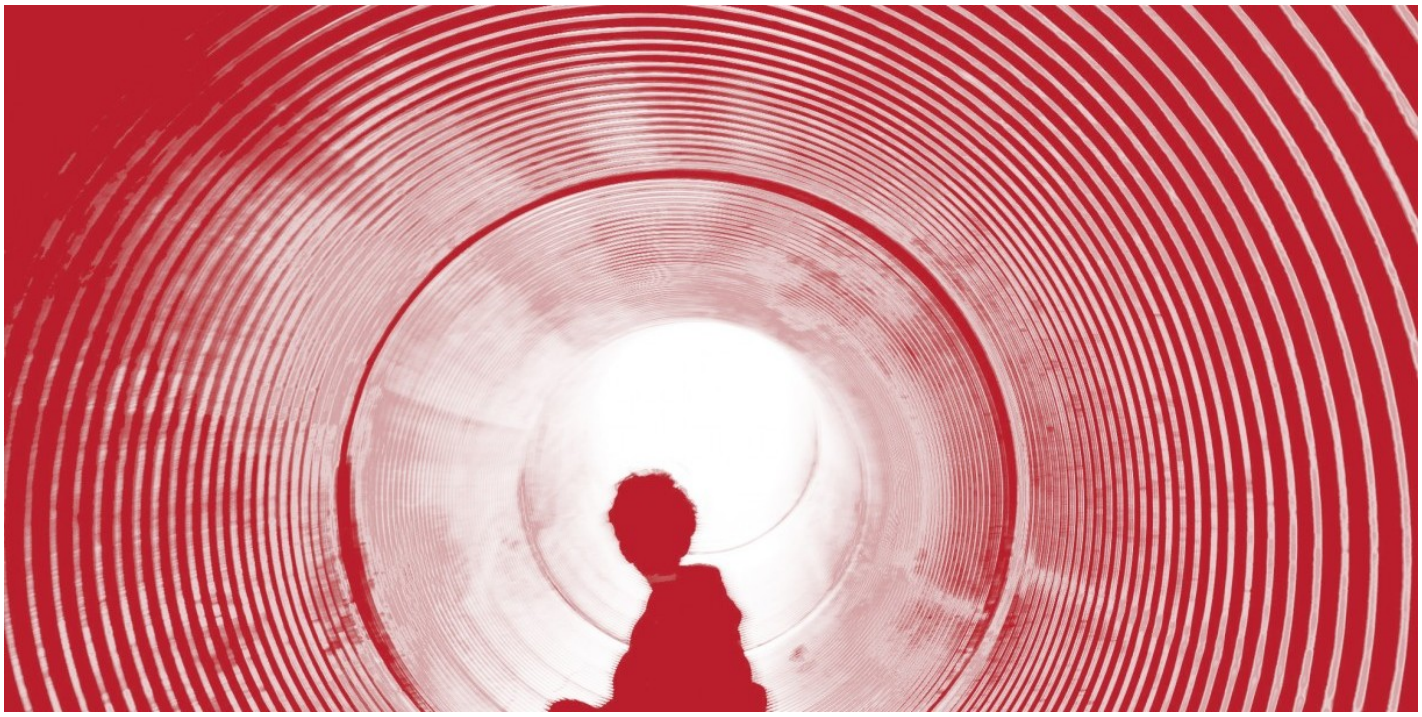

In our last issue of RA Watch (published in October 2020), we flagged that the time will soon come to share the lessons related to the regulatory aspects of human research learnt from the COVID-19 pandemic. How optimistic! We did not imagine the pandemic would last so long … We are still in the tunnel, barely able to see the light at end of the second wave of the pandemic, tired, and worried that a third wave caused by new coronavirus variants could hit.

Yet one year after the pandemic was officially declared by the World Health Organization (on 11 March 2020), we have some good reasons for hope. The first vaccines have proven their high level of efficacy. Three vaccines are now approved for the Swiss market and are progressively being administered, starting with at-risk populations. In addition, 335 clinical trials and research projects on COVID-19 have been approved in Switzerland since the beginning of the pandemic (source: swissethics, updated on 18 February 2021) and most of them are still recruiting patients now. These glimmers of light have appeared thanks to the

unprecedented collective efforts of the pharmaceutical industry, clinical researchers, regulatory authorities, politics, and – let's not forget – health professionals and the public.

So far, repurposed drugs have not been as successful as we had first hoped – except steroid dexamethasone and tocilizumab – and we will need to wait for effective, innovative treatments. Clinical research and authorisation processes for vaccines and treatments have never before been scrutinised so much by the medical community and the general population. Step-by-step scientific progress has never been the subject of so many public commentaries and controversies (e.g. chloroquine and hydroxychloroquine) – sometimes as the result of hope or fears of the unknown, "on air" reporting of the fragmented production of knowledge, scientific debate, and also fake news and unfounded plots that trigger a lot of scepticism. Despite all the debates and because a global pandemic calls for a global response, regulatory organisations have intensified their international cooperation: calls for larger studies, increased transparency, data sharing, common guidelines for vaccines, treatments, diagnostic device development, and new options for regulatory flexibility (e.g. early scientific advice, rolling submission, and fast-track authorisation). However, different approaches to hygiene measures, therapeutic options developments, and authorisations persist across regions (e.g. China, Russia, and Western countries).

In this RA Watch issue, we address various questions about the pandemic in the Swiss context:

- How did we, the CTU network, support the clinical research effort and experience the regulatory aspects of this marathon?
- How did our stakeholders respond to the pandemic: the Swiss National Science Foundation as a major source of funding for research and Swissmedic as the authority responsible for clinical trials with medicinal products approval, the adherence to good clinical practices, and inspections?
- What kind of adapted support did swissethics and ethics committees provide to clinical researchers during the first phase of the pandemic, and how did they safeguard patients' rights in such a crisis context?
- Will adapted operative innovations be opportunities to carry on in the post-COVID-19 future?
- How has the "covidisation" of research affected patients?

In addition, we present two international initiatives in which our CTU network is involved. One initiative with Swiss participation is the World Health Organization's Solidarity trial, which is one of the largest international randomised trials for testing COVID-19 treatments. Another international initiative is the EU-RESPONSE project, which illustrates the cooperation and the innovation amongst European clinical research actors. Finally, we reflect on the pros and cons of human challenge studies, which can be used to more quickly test new medicinal products that protect against SARS-CoV-2 infection. Continuing research is vital because we may still have a ways to go until we reach the end the COVID-19 tunnel …

Enjoy reading (likely at home) this issue of RA Watch and stay safe.

Séverine Méance, RA Watch Editor