Editorial: Fasten your seatbelts! We have speedy twists and turns ahead

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Take away from 2019

In April, we launched the *RA Watch*, intending to face the ever increasing activity and complexity of the regulatory aspects concerning human research in Switzerland – to track changes anticipated and offer them to you as a digest. Indeed, the legislation is undergoing continual development to stay abreast of and adapt to the many societal, technological, political fluctuations and ensure that Switzerland remains competitive.

We have not been disappointed! This timely matter has kept us fully engaged, observing and analysing events. In 2019, we saw the publication of a series of documents on the evaluation of the Human Research

Act (HRA) and its ordinances, which entered into force in 2014; recommendations to adapt the law were published at the end of the year and should be implemented through coming months or years. Additional considerations – linked to the disruptive opportunities brought by new methods and technologies and the potential availability of ever more sharable data – have led to the elaboration of new documents. To mention a few, there are guiding principles and recommendations for registries in human research, the version 2 of the national General Consent (GC), key documents for biobanks, and more. A specific category of products, the medical devices, has also been scrutinised and draft ordinances were published and opened for consultation.

Perspectives for 2020

We're following many pertinent questions: How will human research be shaped in the year to come? How will Switzerland be affected, in concrete terms, by new European regulations, notably the EU General Data Protection Regulation EU 2016/679 (GDPR) and EU Clinical Trials Regulation EU 536/2014 (CTR)? How will the final legislation on medical devices look like?

Increased transparency (in particular, the publication of research results), open science, patient-centricity, larger numbers in patient recruitment, innovative trial designs, real-world clinical data and evidence, data governance, and the modernisation of institutional tools are all key themes that will keep regulators and the human research community on the edge of their seats this year. Let's start the year with an update on the GC.

Stay tuned with us. We'll keep you updated on all the trends, news, and twists and turns that this field will bring in 2020! Till then, take care of yourselves during this special time of coronavirus pandemic.

Latest measures to combat COVID-19

In this exceptional period we would like to thank and value the amazing work from our medical and research colleagues during these challenging times of the coronavirus pandemic. We are doing our best to ensure that we remain operational and continue to best serve the human research community.

Please be aware of the latest news:

Sponsors, investigators and project leaders of clinical trials and research projects in Switzerland must ensure that the studies are conducted in line with the COVID-19 Ordinance 2 issued by the federal government on 16 March 2020 (DE; FR; IT). Please visit the swissethics and Swissmedic specific webpages containing information on the conduct of clinical trials and research projects in Switzerland during the ongoing coronavirus pandemic:

- Joint guidance of Swissmedic and swissethics on the management of clinical trials with medicinal drug products (26 March 2020);
- Addendum to the patients information and consent form of clinical trials during the COVID 19 pandemic (26 March 2020) ;
- List of ongoing and submitted clinical trials and research projects on COVID19.

On 20 March 2020, the European institutions published a guidance on how to manage clinical trials during the COVID-19 pandemic (EN). The International Coalition of Medicines Regulatory Authorities reported pre-

clinical data requirements and reminded the need to understand the theoretical risk that vaccines against COVID-19 enhance the disease prior to starting first-in-human clinical trials on 24 March 2020 (EN).