

# Editorial: A Stormy Season for Medical Devices

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Medical devices are experiencing the blustering winds of change – change that will have a considerable impact on Switzerland. Medical devices in Switzerland represent a CHF 15.8 billion business and hold a leading international position in terms of the country's economy (contributing 2.3% to the national Gross Domestic Product), with 1,400 dynamic, small, medium-sized, and multinational companies thriving in a highly innovative health environment.

With this stormy weather blowing in from the European Union (EU) and certain to sweep right across Switzerland, all players in this field need to get prepared as swiftly as possible. The deadline of May 2020 is around the corner. Those affected must build up strong capabilities to prepare the appropriate dossiers needed, so as to reassure the public and the authorities of the safety and usefulness of both existing and future medical devices. Organisations dealing with medical devices are being obliged to transform

themselves. But how the Swiss authorities will manage their relationships with EU, concerning the harmonisation of rules and mutual recognition agreements, remains hazy.

The DEEP DIVE of this second issue of the RA Watch will help you understand better the regulatory changes coming from the EU and the ongoing revisions of Swiss laws regarding medical devices. You will find out how the clinical evaluations and investigations of medical devices in Switzerland will be affected. Key Swiss stakeholders, including the Swiss Clinical Trial Organisation (SCTO) and its network of Clinical Trial Units (CTUs), swissethics, the medtech industry, and patient associations have shared with our readers their VIEWS AND OPINIONS about this evolution. A concrete CASE STUDY – of an App used in clinical research – illustrates how demanding the new rules will be for investigators who may not even be fully aware that what they are using counts as a medical device.

There is no doubt that high tech will flourish in the future of healthcare. The public is dreaming of high-tech healthrelated devices and these aspirations create a market for it. However, the realisation of these high-tech dreams will depend heavily on trust, and Switzerland is extremely well equipped to face this challenge.

Several hundred readers have subscribed to our newsletter since its début issue in April. Such a flurry of interest confirms a need for the RA Watch and so we thrive on doing our utmost to satisfy you, our readers. We are very pleased to present to you this issue 2, with its fresh, appealing web and print formats. We trust you will find it enjoyable and enlightening, and wish you happy reading.

*Bonne lecture!*