SCTO PLATFORMS

Editorial: COVID-19 challenges and medical registries

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COVID-19 pandemic: Upheaval for regulatory activities related to human research

A lot has happened since our last edition of *RA Watch* in March. Nobody could have imagined how the COVID-19 pandemic would dominate the work of thousands of researchers and regulators and spark an unprecedented global effort (see the Headlines and Happenings section).

Not only regulatory processes but also the way in which human research finds solutions to treat or prevent diseases have been shaken, with politics and egos sometimes interfering too much. At times, this has led to

situations where good and evil coexist. On the one hand, we have been shocked by Russia's and China's declarations to use a vaccine early, with large numbers of their citizens essentially being asked to serve as test subjects as an act of patriotism. One the other hand, we have welcomed the joint efforts of global and regional regulatory organisations and the intensification of international cooperation: calls for larger studies, increased transparency, guidelines for diagnostic devices, treatment and vaccine developments – including end points to consider, increased use of observational studies, and more reflection on regulatory flexibility (e.g. early scientific advice and fast-track authorisation).

Since March, Switzerland has been hurrying – or should we say racing – to start numerous clinical studies and registries on COVID-19. Funding for such projects has been made available. And the regulatory action taken to get projects authorised rapidly has been tremendous. Switzerland's ethics committees and Swissmedic have focused on authorisations and thus been able to approve projects within a couple of days. In addition, guidance on how to manage clinical studies in such situations was provided in April. However, the coordination needed to select and run ambitious research projects was initially missing, which has been problematic when the number of patients available to enroll decreases. To date (28 September 2020), 260 clinical trials and research projects on COVID-19 have been approved in Switzerland – 43 of which are multicentric (source: swissethics).

How will Switzerland contribute to research findings compared to other countries? Will Switzerland get there slowly but surely? Might this pandemic lead to new opportunities to ease regulatory processes while still ensuring patients' safety? The time will soon come to reflect on and share lessons learnt from this period.

Medical registries: Unlocking their full potential in Switzerland

In each issue of *RA Watch*, we focus on a specific topic related to human research – in this issue we have chosen to look at medical registries (MRs). Even if MRs have long been underestimated as a research tool, there is a clear upward trend in the proportion of research projects linked to them (see **Medical registries in Switzerland**). The COVID-19 pandemic has reinforced this trend through the analysis of exceptional clinical routine data.

How are MRs regulated in Switzerland? What recommendations exist for them? What support for registries is currently available or being developed, and what is still missing? What are the key aspects to consider for their success? We address these questions in the News From and Deep Dive sections. We also use specific registries as illustrations: one initiated by a foundation for implantation medicine (SIRIS) and one initiated by a patient association (Swiss MS Registry). This issue of *RA Watch* also contains an example of successful registry governance at a university hospital (CHUV). In addition, we share the results of a national survey on electronic health record (EHR) systems that was conducted by the SCTO's Regulatory Affairs Platform.

We hope you enjoy reading this issue of *RA Watch* and it helps you become more familiar with a promising research tool!

Séverine Méance, RA Watch Editor

BOX 1: MEDICAL REGISTRIES IN SWITZERLAND

In spring 2011, the data, demographics, and quality department (DDQ) of the FMH (Swiss Medical Association) launched a project for a Swiss platform for medical registries. The project aims to promote transparency as well as contribute to networking and coordinating the various Swiss medical registries (MRs)

by documenting online MRs in Switzerland[DE; FR]. The list is updated once a year. **Figure 1** illustrates the increasing numbers of MRs in Switzerland.

Source: Infographics series called Creating a Health-Related Registry Means Investing in the Future! (March 2020), developed and published by the ANQ[EN], FMH[DE;FR], H+[DE;FR], SAMS[DE;FR], and unimedsuisse[DE; FR].

To learn more about MRs, read a recent article by Prof Lübbeke-Wolff (the president of an expert group on registries at the Swiss Academy of Medical Sciences (SAMS) advocating for investing in registries (SAMS Bulletin. 2020; 02–03:2–4[DE; FR]).

Health-related registries in Switzerland

The number of registries in Switzerland is steadily rising. Effective registries promote national collaboration and harmonisation. A number of Swiss registries are attached to international registry networks.

Examples of active registries

- **2020** Swiss National Cancer Registry
- **2012** Swiss National Joint Registry, Hip and Knee
- **2007** Swiss Transplant Cohort Study
- **2000** ▶ Swiss Hepatitis C Cohort Study
  ▶ Swiss Neonatal Network & Follow-up Group
- **1997** ▶ Swiss Clinical Quality Management in Rheumatic Diseases
  ▶ Acute Myocardial Infarction in Switzerland
- **1991** Study on Air Pollution And Lung Disease In Adults
- **1988** Swiss HIV Cohort Study
- **1977** Swiss Cochlear Implant Registry
- **1976** Swiss Childhood Cancer Registry
- **1969** Basel Cancer Registry

Development of active registries