SCTO PLATFORMS

Editorial: Collaborating on the General Consent, the key success factor

Christiane Pauli-Magnus
President of the SCTO
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The use of health-related data and samples from large patient populations carries new promises for the development of novel therapeutic and diagnostic approaches for common and neglected diseases. However, prior to this use, written informed consent of patients who agree to the further use of their data and samples for potential research projects (so-called General Consent, GC) is required under the Swiss Human Research Act (HRA).

In the years following the enactment of the HRA in 2014, university hospitals faced several hurdles. First, paper-based GC processes revealed to be resource-intensive, leading to rather low GC coverage. Second, university hospitals developed individual GC versions with different contents, hindering the easy consolidation of data from different sources for nationwide analysis. Third, electronic approaches to GC through mobile devices was impeded due to the uncertain legal situation concerning electronic signature.

Thanks to the enormous efforts of different stakeholders, the situation has significantly improved over the last two years. Supported by the Clinical Trial Unit (CTU) network, swissethics, unimedsuisse and the Swiss Biobanking Platform (SBP), university hospitals teamed up to develop a national GC version, which is currently being implemented at the different sites. In addition, among other innovative projects, a nationwide electronic GC pilot project successfully passed the test of patient usability and is now ready to be developed into a validated application. Finally, the Federal Office of Public Health (FOPH) recently supported changes in the research ordinance required for the use of electronic signatures.

None of these recent developments would have been possible without a strong spirit of collaboration to make Switzerland an excellent place for high quality, innovative clinical research!

We hope you will enjoy reading the update provided in this *RA Watch* issue.