

Welcome to RA Watch ... and to the world of data protection

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The Regulatory Affairs (RA) Platform of the SCTO is pleased to present to you our first issue of the Regulatory Affairs Watch (RA Watch). Our platform comprises regulatory experts from: the different Clinical Trial Units (CTUs) at the Swiss university hospitals (Basel, Bern, Geneva, Lausanne, and Zurich); the cantonal hospitals of St.Gallen and the EOC Ticino; and the SAKK.

Why do we need another newsletter?

The regulatory field within clinical research is dynamic and undergoing complex, frequent changes, such as the impact of the digital health revolution. The resulting inflation in regulatory activities is often perceived as an increased burden by professionals involved in human research. To remain competitive and avoid misunderstandings, we need to share simple yet also comprehensive information among the human research community in Switzerland, such as practical case studies.

This newsletter will deliver a digest of essential information at regular intervals on human research-related regulatory topics (existing and in development), concerning Switzerland and other countries, if relevant. Our target readership spans across the full spectrum of human research professionals: from investigators, regulators, members of ethics committees, professional and academic associations, to, last but not least, patient representatives.

In this issue, we raise the hot topic of data protection in human research. With the European General Data Protection Regulation (GDPR) now in force, Switzerland – being part of an open world – cannot remain unaffected by the considerable changes it brings. Our Deep Dive and Views and Opinions sections address some relevant and concrete questions encountered in clinical research.

In future issues, the RA Watch will focus on other interesting topics, like the impact of the EU Medical Devices and Clinical Trial Regulations, electronic Health Record Systems, national general consent and more... We hope you enjoy reading our newsletter.

Your constructive feedback is most welcome.

