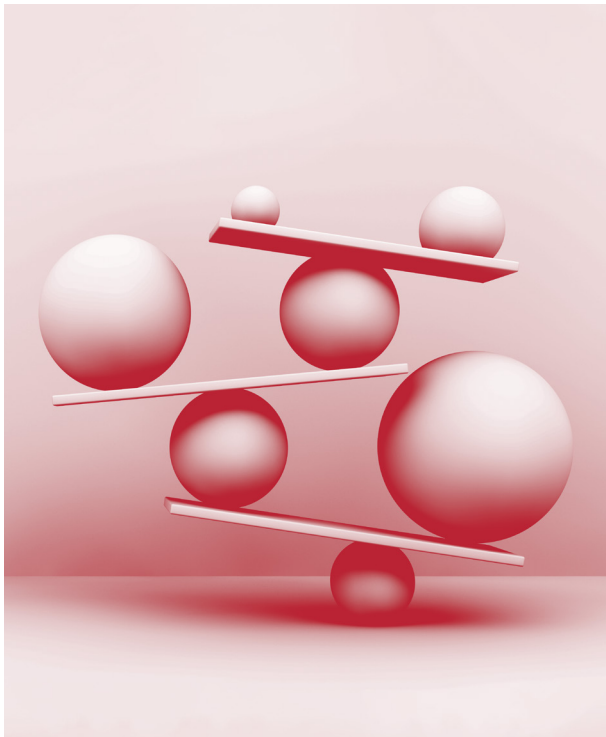


EDITORIAL



KEEPING A BALANCE BETWEEN DATA PRIVACY AND DATA SHARING IN CLINICAL RESEARCH

Achieving balance in our frantic daily lives is not easy. Weighing up pros and cons requires time and information on the risks involved and the potential consequences of doing – or not doing – something. This balancing act also takes place in clinical research, especially when considering the immanent pressure on researchers to “publish or perish”.

Sharing research data that are new, of interest to the scientific community, of good quality, and that favour reproducible research is a welcome call. However, clinical research by nature deals with sensitive data that, if disclosed, can potentially have huge consequences on an individual’s life. On top of legislation aimed at protecting citizens’ data in general, additional laws, ordinances, guidelines, and guidance provide the clinical research community with a full framework aimed at protecting individuals’ privacy and health and respecting their dignity. In addition, the Swiss National Science Foundation (SNSF) has created practical documents such as guidelines and a [template](#) for creating a data management plan (DMP), and the Swiss Clinical Trial Organisation (SCTO) has published a [guidance document](#) on sharing data from clinical research projects in order to help researchers anticipate the life cycle of their research data and make appropriate decisions when sharing research data.

When managing research data, researchers can face a series of dilemmas: How to respect privacy and share data at the same time? How to responsibly balance protection and the use of clinical research data? It is not ethical to publish personal data, even when anonymised, without consent (with a few exceptions). But it is also not ethical to *not* share data that could facilitate medical progress and help other human beings. Therefore, should a researcher favour the individual or the community? In the end, it is all a matter of perspective. Perception will vary between individuals, depending on their age, education, health condition, and many other personal factors that can tip the scales one way or the other. The scales can even tip in opposite directions throughout a person’s life, reflecting changes in the factors that influence a person’s decision-making in any given situation. Therefore, researchers need to be continually informed about the relevant regulatory background and the ethical and practical factors to consider when thinking about how to make decisions about data sharing and data protection.

Our initial aim for this issue of *Regulatory Affairs Watch* was to focus exclusively on clinical research data, meaning data obtained from clinical studies or clinical trials. However, we decided we also needed to address the elephant in the room: the further use of health data

from routine clinical activities. The articles in this *RA Watch* lead you through different factual aspects of data sharing and data protection, present various opinions and points of view, and contain examples and experiences related to the topic. This *RA Watch* is intended to help inform your opinion on this tricky topic.

- **DEEP DIVE:** As a starting point, the Regulatory Affairs Platform (RA Platform) team provides an overview of the various requirements that apply to data privacy and data sharing in clinical research conducted in Switzerland.
- **VIEWS AND OPINIONS:** Diverse approaches are reported here: a regulatory analysis from the Cantonal Ethics Committee Zurich, a legal view of the topic from a specialised lawyer, and a perspective from industry about the challenges and opportunities of data sharing.
- **NEWS FROM:** The news corner covers the approach and concepts governing the initiation and provision of data sharing services of one of the best known Swiss data repositories (Zenodo at CERN) and offers advice on preparing data to be shared. Two ways of taking advantage of the scientific benefits of shared data are also presented: the highest level of evidence through meta-analyses by an epidemiological expert at the University of Bern and the research on research (RoR) approach by the STEAM working group.
- **CASE STUDY:** Last but not least, an illustration of a researcher's experience with sharing real-world data is shared by the man behind the data of one of Switzerland's greatest successes in observational research: the CoLaus|PsyCoLaus cohorts.

After almost one year of coordinating the RA Platform *ad interim*, it is time for me to hand over *RA Watch* to a new, permanent RA Platform coordinator and pursue other opportunities. It was truly a pleasure to prepare this new issue. I hope that you enjoy reading it and that it will help you keep your balance!



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Opinion

Data sharing and data privacy: what an inherently antithetical, self-contradictory topic! How and why should researchers share what one would normally rather keep undisclosed – especially in the context of clinical research, which by nature deals with sensitive health-related data? The difficult nature of this topic was reflected by some pushback the *RA Watch* team experienced when requesting contributions for this issue (it is too controversial, it is too early to have a (publishable) opinion or policy, it is too much of a work in progress, etc.). While most experts in our field take a more cautious approach to data sharing, some other more confident stakeholders consider the existing data protection policies and systems to be sufficiently safe to upscale data sharing across multiple sources, from sport watches to genomic data to health records. Is there any zero-defect system? What about cyber-attacks? And while the UK's National Health Service (NHS) demonstrated to the world the power of data sharing in COVID-related research, it has also been challenged by a BMJ audit detecting hundreds of data privacy breaches. And should we openly share data in a world in which Switzerland's Federal Data Protection and Information Commissioner (FDPIC) joined the Court of Justice of the European Union (CJEU) in invalidating their Privacy Shield data transfer pacts with the US? What protections for data privacy are possible without impairing research?

These questions on data privacy and data sharing do not have easy answers. In this issue of *RA Watch*, our contributors (who are generally in favour of data sharing since they are involved in research) tackled many of the challenges, potential advantages, and pitfalls of data sharing from different angles. Their contributions can help shape the ongoing dialogue on this controversial topic. Happy reading!



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