



REGULATORY AFFAIRS WATCH

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Unique, credible, and regular updates on regulatory topics relating to human research



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WELCOME TO RA WATCH... AND TO THE WORLD OF DATA PROTECTION

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. You can subscribe for free at this [link](#).

Séverine Méance and Laure Vallotton
of the SCTO Regulatory Affairs Platform

DEEP DIVE

The European General Data Protection Regulation (GDPR): interactions with clinical research

The latest in data protection in EU

On 25 May 2018, the European General Data Protection Regulation (GDPR; [Regulation \(EU\) 2016/679](#)) came into force, giving data protection in and, under certain conditions, outside the EU territory, a new focus. In parallel, it introduced several new standards. GDPR replaces the European Data Protection Directive 95/46/EC and aims to harmonise data privacy laws across Europe. This regulation applies to the processing of personal data from living individuals (GDPR, art. 2), carried out by data controllers/processors, whether residing in the EU or beyond its borders. It pertains specifically to the processing of personal data of subjects who are residing in the EU while providing them with goods or services, or while monitoring their behaviour (GDPR, art. 3).

GDPR also defines *special categories* of personal data (previously called “sensitive personal data”, including among others: genetic data, biometric data, health-related data, data revealing racial or ethnic origin, etc.) for which appropriate safeguards must be put in place in order to ensure lawful, fair, and transparent data processing (GDPR, art. 9). Such safeguards include for instance obtaining a free, voluntary, and informed consent, the designation of a Data Protection Officer (DPO), and the coding or pseudonymisation of data.

The primary objective of GDPR is to ensure that the privacy of data subjects is warranted and their personal data protected. For this purpose, GDPR empowers all data subjects with certain rights, through which they can be assured that the data controller is not misusing their personal data. **Eight fundamental rights** apply to data subjects under GDPR, namely:

- 1) *Right to information* (GDPR, arts. 13–14): The data subject is entitled to ask the data controller for information about what personal data (about them) is being processed and the rationale for such processing.
- 2) *Right to access* (GDPR, art. 15): The data subject is entitled to get access to their personal data being processed.
- 3) *Right to rectification* (GDPR, art. 16): The data subject is entitled to ask for modifications to their personal data, should they believe that this personal data is not up-to-date or is inaccurate.
- 4) *Right to erasure* (“*right to be forgotten*”) (GDPR, art. 17): The data subject is entitled to ask at any time for the deletion of their data, subject to certain rules and exceptions.
- 5) *Right to restriction of processing* (GDPR, art. 18): The data subject is entitled to limit the processing of their personal data, also subject to certain rules and exceptions.
- 6) *Right for data portability* (GDPR, art. 20): The data subject is entitled to ask for the transfer of their personal data (to themselves or to another controller), in a machine-readable electronic format.
- 7) *Right to object* (GDPR, art. 21): The data subject is entitled to object to the processing of their personal data.
- 8) *Right to object to automated processing* (GDPR, art. 22): The data subject is entitled to object to a decision based on automated processing.

In addition to the abovementioned new rights held by data subjects, the following *changes* are introduced with GDPR:

- the *extraterritorial applicability* of the regulation (GDPR, art. 3): GDPR jurisdiction is extended as it applies to all data controllers (including companies or institutions) processing personal data of EU subjects, regardless of the data controller’s location;
- the concept of *privacy by design* (GDPR, art. 25): this concept calls for the inclusion of privacy at the initial design stages and throughout the complete development process of systems that involve processing of personal data;
- the designation of a *Data Protection Officer* (GDPR, arts. 37–39) is required where processing operations entail regular and systematic monitoring of data subjects on a large scale, or of special categories of data pursuant to art. 9 (thus, including data concerning health);
- significant *fines* and *penalties* in case of infringement of GDPR (GDPR, arts. 83–84).

As GDPR is of a general nature, no specific field of application is addressed. This raises potential issues, in particular for clinical research.

Data protection in Switzerland, under revision

In Switzerland, the various aspects of data protection are regulated through the Federal Act on Data Protection ([FADP](#)) and respective cantonal laws. Clinical research data protection specificities are covered by the Human Research Act ([HRA](#)) and its ordinances ([ClinO](#); [HRO](#)). As of end-April 2019, the Swiss Parliament is currently revising the FADP to take account of current technological and societal evolutions and to address the alignment with GDPR. Ideally the revised FADP should bring Switzerland closer to GDPR standards, allowing for a prolonged recognition of Switzerland as a country with an adequate level of data protection ([Decision 2000/518/EC](#); GDPR, art. 45). The revised FADP is expected to enter into force in 2020. In the meantime, the Federal Data Protection and Information Commissioner provides a [regularly updated document](#) detailing consequences of GDPR for Switzerland in general.

Data protection in clinical research, generally

As regards clinical research, data protection is intended to ensure that participants' data is handled appropriately, i.e. that the confidentiality of their records is protected (ICH GCP 2.11). Participants' consent – their agreement to participate in a study and for their data to be used in that study and/or subsequent studies – is obtained via consent forms, prior to study enrolment. Specific processes must be established to ensure consent is given freely and can be withdrawn at any stage. The number of staff with access to study data should be limited, to ensure purposeful and appropriate data handling. In addition, study participants hold certain rights regarding the use of their data, such as: viewing their data (HRA, art. 8), having it corrected if inaccuracies are identified, and having it anonymised should they withdraw their consent (ClinO, art. 9; HRO, art. 10). To protect the participants, study data is generally coded at the time of collection.

The European clinical research community has already experienced many concrete changes and identified potential hurdles (see the article by Demotes-Mainard, Cornu, and Guérin highlighted in [Views and Opinions](#)). Among them, the newly introduced “**right to be forgotten**” (GDPR, art. 17) raises some challenges to clinical research. Under GDPR, this right means that at any time data subjects have the right to withdraw their previously granted consent to participate in a study, they can also withdraw their agreement to the processing of already acquired data. Moreover, they can request for their data to be deleted (“forgotten”) and used no further. The application of this right in clinical research is problematic for two reasons.

Firstly, it contradicts the GCP requirements necessitating that changes to source data remain traceable, the original entry remains unobscured, and explained, if necessary (e.g. via an audit trail) (ICH GCP 4.9.0). Secondly, the purpose of clinical research itself comes under scrutiny: if data can no longer remain in the database (even in anonymised form) and is prohibited for further use, both the overall quality of research itself could be impaired and study results biased. Moreover, it might affect the safety of the participants asking to be “forgotten”, as well as the safety of the study population as a whole (as it might affect safety analyses). Consequently, consideration should be given to clinical trial data, firstly, as being classified as “special” data category under the GDPR (art. 9) and, secondly, relating to the scientific consistency of the trial to elicit derogation (legal exemption) to the subject's otherwise prevailing right to erasure (in application of GDPR, arts. 17.3.d and 89.1). The current law is, however, not explicit on the application of this consideration.

The implications of GDPR for clinical research in Switzerland

Although GDPR is not directly applicable to Switzerland, its new requirements add complexity. One of the most substantial changes – seemingly simple, at first consideration – carries a substantial impact: the **territorial scope expansion of GDPR beyond EU borders** (GDPR, art. 3). The focus of GDPR is data protection in general, aiming thus to address the (mis)use of data. Territorial expansion is meant to ensure that data controllers respect EU data protection laws for EU residents, irrespective of where the data controllers are based or where the data is processed (for example, on a server located outside of the EU). Nevertheless, this step towards better control of data use and storage may potentially impact clinical research data processes.

A potential illustration relates to (multicentre) clinical trials or study projects for which Switzerland and EU countries are involved: according to the territorial scope expansion, GDPR should be enforced for any EU residents participating in an EU- or Swiss- sponsored trial, even if the location of the trial is in a Swiss centre. Accordingly, in case of non-compliance with GDPR requirements, a trial conducted at sites in the EU (and/or enrolling EU residents as participants) could face the risk of being fined.

Another significant change relates to the formal introduction of a DPO. Despite the clear definitions of the responsibilities of such a DPO, interpretation regarding the details and practical application of their obligations are rather open (GDPR, arts. 37–39). GDPR requires a DPO to be in place where large-scale monitoring is performed, to ensure GDPR is warranted for all participating EU residents. But it is not explicitly defined whether every study centre requires its own DPO and if it is acceptable from an EU point of view for a DPO to reside outside the EU (e.g. at a Swiss sponsor site).

Summary and perspectives

Uncertainties remain in what extent is GDPR really applicable in the context of clinical research in Switzerland. Which potential issues can we expect and which will be the thorniest? How serious is the threat of financial fines to those sponsors who cannot demonstrate clear adherence to GDPR? We still need to cumulate experience to answer such pending questions.

In theory, Swiss standards are equivalent to EU standards; so the clarification of obligations could be managed through establishing adequate contracts between EU sponsors and their Swiss study sites. But with little room for interpretation, Swiss trial centres might already feel uncomfortable acting with such uncertainties. Luckily, with much progress underway, the coming months will bring greater clarity on these questions.

At the SCTO Regulatory Affairs Platform, we have set up a project team, dedicated to follow closely this topic. Project team: Christina Huf (CTU Bern, Lead), Sonia Carboni (CTU Geneva), Laura di Petto and Cristiana Sessa (EOC Ticino).

Please send your questions or comments to the RA Platform (regulatoryaffairs@scto.ch).

IEWS AND OPINIONS

While developing appropriate laws to serve Switzerland, we can learn from and build on current EU experiences of how GDPR affects clinical research.

Exploring the broader EU setting

How will the new European data protection regulation affect clinical research? And what recommendations can be derived, to make it run more smoothly? These questions, among others, were addressed in a recently published article by Demotes-Mainard, Cornu, and Guérin (Therapie. 2019 February; 74(1), 31-42). It was published originally in [French](#) and translated into [English](#).

The article is an outcome of a roundtable held in 2018 with French representatives from the European Clinical Research Infrastructure Network (ECRIN), clinical scientists from university hospitals and public research organisations, the industry, and authorities, on the topic of data protection. The objectives were to identify problematic areas, including those in the need for clarification, and to make related recommendations to promote clinical research, while ensuring a high level of patient protection. The authors outlined comprehensively all stages of clinical research affected by GDPR (see Table 1, reproduced with permission).

Table 1 Stages of clinical research impacted by the GDPR.

| Point of impact | Explanation/types of database |
|--|---|
| Site selection, investigator selection | A site/investigator can be selected based on its past publications, its activity and its patient population |
| Agreement between sponsor and investigational site | Agreement needed between data controller (DC) and processor |
| Patient selection | Patients can be selected from healthcare databases: PMSI, data warehouses |
| Informed consent | GDPR information updated, broad consent, re-consent, evolving consent, dynamic consent, e-consent |
| Cohort/registry data | Specific studies or clinical trials using these databases |
| Data from national databases | |
| Electronic health records | Data on care is inserted into research databases and clinical trial CRFs |
| Electronic data capture | Connected objects, e-questionnaires |
| Data sharing (FAIR) | With medical journal reviewers, and made available to the community |
| Reuse of data | Access to existing databases |

CRF: case report form; FAIR: findable, accessible, interoperable, reusable; GDPR: general data protection regulation; PMSI: program for the medicalization of information systems.

The authors also made recommendations falling into three categories: the exercise of individuals' rights, streamlining administrative procedures, and a more open relationship with the international environment.

Recommendations for fostering international cooperation

The authors are calling for Europe-wide harmonisation of data protection regulations and procedures. It is difficult at present to ascertain to what extent the GDPR and the obligations of multinational clinical trial sponsors are being implemented in European countries.

Regarding their obligations to ethics committees, foreign sponsors should be told how to proceed, including by making the relevant documents available in English, so as to facilitate their international projects. Various European partners are preparing codes of conduct to help clarify how the GDPR applies to multinational data processing.

The authors concluded that, at this stage, the constraints of GDPR are still imperfectly defined. These constraints should, however, not compromise the opportunities available to clinical research: transparency and data-sharing according to the principles of open science, the possibilities afforded by big data, and the potential to reuse existing data (such as hospital data, health databases, study data cohorts, and registries).

From the EU to Switzerland within Europe

Euresearch, a Swiss non-profit association facilitating national participation in the EU Framework Programme for Research and Innovation, made "[Ethics and Data Protection in Horizon 2020](#)" a highlight of its February 2019 newsletter.

With the GDPR aiming to harmonise data privacy laws across Europe, those Horizon 2020 projects with sites in Switzerland often face related legal and ethical challenges. To obtain support with such a project, please contact the [Euresearch office in your region](#), or the national contact point for [health](#) or [ethics](#).

HEADLINES AND HAPPENINGS IN SWITZERLAND

SCTO Forum "Clinical Research"

Navigating towards good clinical research data governance

- 30 January 2019: Ninety participants convened to learn about and discuss: What is the current level of organisation of clinical research data at the SCTO member hospitals? How is this conducted abroad? How and by whom should patients and the public be informed about how their data is governed? And how can we combine our skills and strategies to forge constructive yet innovative headway? The programme, presentations, and a summary report are available on the [SCTO website](#).

Annual roundtable meeting between the SCTO, swissethics, and Swissmedic

- 12 February 2019: These organisations met to share information, respectively, about their current projects. They discussed concrete subjects, including national general consent, the electronic submission of clinical trial applications for medical devices, and data protection.

swissethics

- 10 January 2019: Publication of a "**Position paper on how to manage incidental findings in medical research**" ([DE](#); [FR](#); [IT](#)). It is necessary to carefully consider when, how, and which results to communicate to patients.
- 19 February 2019: Publication of "**Guiding principles for registries in human research**" ([DE](#); [FR](#)). The document explains which data collections in human research are subject to authorisation by an ethics committee and when the consent of the participants or their information on the right to dissent is required. The statement also brings the proposal for a technical validation of a registry as an early step in a research project.
- 22 February 2019: Publication of "**Version 2 of the national General Consent (GC)**" ([DE](#); [EN](#); [FR](#); [IT](#))

together with unimeduisse. Swissethics strongly supports the continuous further development of the version 2 of the GC after having gathered experience on its use, at a later point in time (source: [swissethics](#)).

Swissmedic

- Dr Petra Dörr from Swissmedic was elected as Vice-president of the General Assembly of the **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)** during the November 2018 conference (source: [ICH website](#)).

Clinical trials of medicinal products

- 15 December 2018: Publication of working instructions "**Guideline on temporary authorisation to use an unauthorised medicinal product**" ([EN](#)). A temporary authorisation under restricted conditions can be granted to the sponsor of a clinical trial approved in Switzerland, to use the medicinal product without marketing authorisation in patients outside of this trial.
- 20 December 2018: Updated working instructions "**Instructions for submitting changes and for reporting during the course of a clinical trial**" ([EN](#)) for category B and C trials, associated with two updated forms.
- 1 January 2019: Updated "**Guideline on clinical trial application dossier**" ([EN](#)) for medicinal products.

Clinical trials of medical devices

- 19 December 2018: Publication of an "**Information sheet on clinical trials with medical devices**" ([EN](#)): intended for sponsors, CROs, and clinical investigators. It provides guidance on the authorisation process, reporting requirements of sponsors, and the surveillance of clinical trials by Swissmedic.

- 19 December 2018: A new form on “**Reporting serious incidents for medical devices**” ([EN](#)), for manufacturers and placers on the market, was published by the European Commission. This form can be used for submitting reports to Swissmedic with immediate effect (source: [Swissmedic](#)).

Federal Office of Justice (FOJ)

- 30 January 2019: **Adoption of Schengen Federal Data Protection Act (DPA)**

The Swiss Parliament has dissociated the drafting of the federal law implementing Directive (EU) 2016/680 with regard to the processing of personal data in the field of criminal purposes from the revision of the Data Protection Act. The first entered into force on 1 March 2019. The revision of the DPA is currently ongoing at Parliament level (probably entering into force in 2020). It aims, in particular, to adapt data protection to the digital era and to strengthen the rights of citizens. The purpose of adapting legislation to EU law is to ensure the transmission of data between Switzerland and the EU Member States without further hindrance (source: FOJ; [DE](#); [FR](#)).

Federal Office of Public Health (FOPH)

- 2 February 2019: From end-2020, the new **Regulation EU 536/2014 (CTR), governing clinical trials on medicinal products**, will enter into application in the EU. These rules will affect clinical trials in Switzerland. The FOPH assesses the impact and closely monitors further developments (source: [FOPH](#)).

Swiss National Science Foundation (SNSF)

- 1 February 2019: Science Europe has published recommendations on **Research Data Management**. Many funding organisations have started to request data management plans as part of their open research data policies (source: [SNSF](#)).

eHealth Suisse

- The **Electronic Patient Record (EPR)**: eHealth Suisse will produce in 2019na series of related tools. In addition, the interlinking of other data will be encouraged (source: eHealth Suisse; [DE](#); [FR](#)).
- The Swiss federal law concerning EPR comes with two federal and one departmental ordinances. The FOPH plans to supplement these requirements by the summer of 2019 (source: eHealth Suisse; [DE](#); [FR](#)).

Swiss Academy of Medical Sciences (SAMS)

- 15 January 2019: “**Free access to scientific literature**” ([EN](#)). The Cochrane Library is accessible to the broader public in Switzerland, including health professionals, wishing to obtain reliable information.
- 25 February 2019: Publication of “**Patient, doctor, big data. Who has the power of definition?**” ([DE](#); [EN](#); [FR](#)).
- 4 March 2019: Publication of new recommendations “**Ethics training for health professionals**” ([EN](#)).
- 18 March 2019: Publication of “**Support of young clinical researchers – existing instruments and needs**” ([DE](#); [FR](#)) (source: [SAMS News](#)).

Schweizerische Ärztezeitung / Bulletin des médecins suisses

- 30 January 2019: Publication of an article on “**Registers for Health Care Research and Quality Assurance**” ([DE](#); [FR](#)).

Swiss Biobanking Platform (SBP)

- 10 January 2019: The SBP is testing the Biobank SQAN (Solution for Quality Assessment and Normalization), an innovative web-based solution to help biobanks efficiently identify areas and means of improvement (source: [SBP News](#)).

HEADLINES AND HAPPENINGS ABROAD

EUROPE

European Medical Agency (EMA)

- The agency closed its offices in London and is **operating from Amsterdam** as of 11 March 2019.
- EMA outlined five strategic goals in its draft “[Regulatory Science to 2025 strategy](#)” (human and veterinary medicines) with a focus on: fostering clinical trial innovation, optimising capabilities in modelling and simulation, as well as exploiting Artificial Intelligence and investing in special populations, among other objectives. This document entered in a six-month consultation period ending on 30 June 2019.
- EMA, together with the Heads of Medicines Agencies published [core recommendations on big data](#) in February 2019. The consultation is open until Mid-April 2019. The agencies find European

regulators not yet prepared to embrace advanced analytics for drug development.

- Revision of the EMA’s “[Guidance on its clinical data publication policy](#)”.
- A report published in February 2019 by TranspariMED and Health Action International indicates that over 50% of due clinical trials are missing results on the EMA EU clinical trials register (EUCTR). Approximately the same gap exists with other registries such as ClinicalTrials.gov (source: [Outsourcing-pharma](#)). On the same topic, the UK government is considering sanctions on sponsors or investigators who fail to comply with transparency rules (source: *The Advisor*, issue 438).

- First [EU guidance on new rules affecting medical devices](#), from a series of guidance documents that should help applicants prepare for the new EU regulations on medical devices.

European Commission (EC)

- November 2018: Publication on “[Ethics and Data protection](#)”. This document aims to raise awareness in the scientific community.
- **Real-world clinical data** can generate insights and evidence. The [EHDEN](#) (European Health Data & Evidence Network) project was set up to provide a new paradigm for the discovery and analysis of health data in Europe.

European Data Protection Board (EDPB)

- January 2019: The EDPB provided an opinion ([Opinion 3/2019](#)) clarifying the interplay between the GDPR and the CTR. It allows the update of processes to conduct clinical trials that comply with both regulations.

Heads of Medicines Agencies (HMA)

- February 2019: Publication of [recommendations for complex clinical trials](#) by the Clinical Trials Facilitation and Coordination Group. Complex trials can be used for the development of personalised medicines, for instance. They may have separate individual clinical trials and extensive prospective adaptations.

USA

US FDA

- [Modernising clinical trials](#) is an agency priority. The FDA is stepping up its efforts to encourage wider adoption of new clinical trial methods. The objective is to help drug-makers and clinical researchers to advance precision medicine, patient protection, and more efficient product development.
- **Real-world data and evidence:** FDA laid out the agency's priorities for use of real-world data and evidence. It is currently developing a guidance document (source: [US FDA](#)).

- **Final guidance** on “[Enrichment strategies](#) for clinical trials to support demonstration of effectiveness of human drugs and biological products”.
- **New draft guidance documents** on:
 - “[Assessing the effects](#) of food on drugs in clinical trials”
 - “[Bioavailability studies](#)”
 - “[Developing and submitting](#) proposed draft guidance relating to patient experience data”
 - “[A risk-based approach to monitoring](#) of clinical investigations”.

EVENTS AND PUBLICATIONS

Events

- Webinar on ethics compliance under GDPR in Horizon 2020 projects, held in **March 2019**, available for public access from [Health NCP Net](#).
- [RAPS Regulatory Conference Europe](#). **Brussels, 13–14 May 2019**.
- [ECRIN-F-CRIN conference to celebrate the International Clinical Trials Day \(ICTD\)](#). **Paris, 20 May 2019**.
- [9th Symposium of the SCTO](#). Emerging methodologies and measures in clinical research. **Geneva, 12 June 2019**.
- [ECCRT Data Transparency Conference](#), Demystifying Clinical Data Transparency: Lessons Learnt So Far. **Brussels, 12–13 September 2019**.
- [Interactive webinar](#) on the European Clinical Trial Regulation 536/2014, run by the European Centre for Clinical Research Training (ECCRT), periodically and with registration, from **April to October 2019**.

Books and publications

- [A Guide to European Data Protection](#) published by Canary and written by L. Tofte Hemmingsen, a quality assurance professional with many years' experience in the pharmaceutical and healthcare industry. The book comes with online training.
- [DKForum no. 12](#) from the Departement Klinische Forschung Basel, with a focus on data governance (DE).
- SAMS Bulletin, *Responsible data sharing* ([DE](#); [FR](#)).
- Publication of the Swiss Medical Forum on *The themes of the ethics consultation*, including cases from Basel-based institutions ([DE](#); [FR](#)).

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Sources of information

- We gather news on regulatory topics linked to human research.
- We regularly read newsletters and visit the websites of relevant sources, including: the regulatory authorities in Switzerland, Europe, and USA; ICH and WHO; the major Swiss academic organisations and health associations; and professional associations.
- Additionally, we review major clinical research journals.

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