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**Experiences with the 2021 changes to  
the medical device regulatory framework**

# REGULATORY AFFAIRS WATCH

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# EDITORIAL



## NAVIGATING THE 2021 CHANGES TO THE MEDICAL DEVICE REGULATORY FRAMEWORK

How time flies! In October 2019, we published our [second issue of Regulatory Affairs Watch](#) – dedicated to the new medical device (MD) regulatory environment – ahead of the simultaneous entry into force on 26 May 2021 of Switzerland’s [Ordinance on Clinical Trials with Medical Devices \(ClinO-MD\)](#) and the European Union’s [Medical Device Regulation \(MDR 2017/745\)](#). Notably, 26 May 2021 was also the day on which Switzerland’s Federal Council decided to end negotiations on the institutional framework agreement with the EU! The ClinO-MD was updated a year later to incorporate changes linked to the specifics of in vitro diagnostic devices in alignment with the EU’s related [In Vitro Diagnostic Medical Devices Regulation \(IVDR 2017/746\)](#), which entered into force on 26 May 2022.

At the time, the anticipated changes raised many questions: How would medical device manufacturers acting as study sponsors manage this new regulatory situation? How would international trials be conducted? How would academic researchers navigate this new regulatory complexity? How would ethics committees handle the new categorisation of studies? How would the regulatory authority Swissmedic respond to these changes? And finally, how would patients and potential participants in medical device studies perceive all of these changes? This community of medical device stakeholders found itself in a completely reshaped regulatory world, facing many unanswered questions. And for all stakeholders, it was uncharted territory...

Learning how to navigate through this new regulatory world has required time. After two years of accumulating experience with the new MD regulations, stakeholders were asked by the *RA Watch*’s editorial board to share their experiences and to comment on the challenges they still face.

- **DEEP DIVE:** Regulatory progress in clinical research often seems more reactive than proactive. That is why we start off this issue of *RA Watch* with an article from the French patient organisation Ligue contre le cancer (LCC, league against cancer) that looks back at the medical device health scandals that triggered regulatory changes. The article also contains patients’ perspectives on the new European regulatory framework.
- **FEEDBACK FROM:** Ethics committees and regulatory authorities play a key role in the regulatory process. Swissmedic and swissethics have remained at the forefront of this process, and they inform *RA Watch* readers how they prepared for the new framework and the tools they have made available to their stakeholders, sponsors, and investigators.

● **VIEWS AND OPINIONS:** The Swiss medical technology sector has not only been directly affected by the regulatory paradigm shift, but it has also felt the effects of Switzerland's shift to third country status with the EU and the resulting hurdles to the cross-border commercialisation of medical devices. In our first Views and Opinions article, Swiss Medtech reports on how the industry prepared for these new conditions and how it is now coping with and adapting to them. The new regulatory framework has undoubtedly strengthened the experimental validation of medical devices as well as the identification and reporting of safety issues. Yet at the same time, it has introduced additional complexity. Nevertheless, the increased involvement of patients in all stages of development will certainly help to prevent health-related MD issues such as those that triggered the recent MD regulatory changes. In our second Views and Opinions article, a patient advocate argues why patients' input into MD development is essential and presents concrete ideas on how to increase patient engagement.

● **CASE STUDY:** The new regulatory framework does not prevent researchers from conducting exploratory observational research, for instance at an early conceptual stage for a medical device. We report on a case study about an innovative device that could be categorised within the observational research framework (Human Research Ordinance (HRO), Chapter 2) since it does not impact research participants' health.

Some time has passed since we published the pilot issue of *Regulatory Affairs Watch* in December 2018 – and we are now publishing issue eight! After initiating the concept of this publication five years ago and overseeing all eight issues, backed by the SCTO's Regulatory Affairs Platform, my time with *RA Watch* has come to an end. As part of a local institutional reorganisation, I must step down from my responsibilities within the SCTO's CTU in Lausanne and the RA Platform. In just a few years, *RA Watch* has become a nationally registered and referenced Swiss publication, meeting almost all the criteria of a diamond-level open-access journal. It has a following of over 500 subscribers and also attracts readers on the SCTO's [Tools & Resources](#) website, most of whom are clinical research professionals.

I would like to thank all those who have contributed to *RA Watch's* success. This includes authors, with a special mention of our counterparts at Swissmedic and swiss-ethics (whom we have invited to contribute to almost every issue); patients and representatives of the public; RA Platform members; the SCTO's Executive Office, and in particular Pascale Wenger, who serves as the RA Platform's liaison officer and is currently the RA Platform's coordinator *ad interim*; and former platform coordinators Laure Vallotton, Séverine Méance, Loane Warpelin-Decrausaz, Isabelle Guilleret, and Olga Deckarm. And a special thanks to our publishing team under the excellent leadership of our publication coordinator Meg Züblin!

Happy reading and long live *Regulatory Affairs Watch*!



**Marc Froissart**, *RA Watch* project lead and editor  
Research and Education Department of Lausanne University Hospital (CHUV) and University of Lausanne (UNIL)

## DEEP DIVE



### REGULATORY DEVELOPMENTS IN THE MEDICAL DEVICES SECTOR: A LONG AND DIFFICULT JOURNEY

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Because the development of medical devices, device users, and the devices themselves often cross borders, medical device regulations in Switzerland are closely aligned with those of the European Union. Therefore, the *Regulatory Affairs Watch* editorial team wanted to hear first-hand from a European stakeholder who has been involved in this matter since the events that triggered the changes to European medical device regulation. In this Deep Dive article, Catherine Simonin, MD, who is actively engaged in France's Ligue contre le cancer (LCC, league against cancer) and the overarching national patient organisation France Assos Santé, discusses some of the drivers of regulatory changes for medical devices. The LCC has long been advocating for medical device legislation to focus more on patient safety, and the effects of its advocacy efforts can be seen in the EU's changing legislative landscape. Using a Q&A format, Catherine Simonin also presents the perspective of patients and patient organisations on the EU's recent Medical Device Regulation.

European law has evolved to guarantee greater safety for patients who receive or use medical devices (MDs). The new EU [Medical Device Regulation](#) (MDR), which governs MDs and came into force on 26 May 2021, is an important step forward in making devices safer to use and thus in safeguarding patients' interests. In particular, the MDR upgrades the requirements for demonstrating that benefits outweigh risks and imposes stricter post-market surveillance.

Since the text was published in 2017, the [French National Agency for Medicines and Health Products](#)

[Safety](#) (ANSM) has been supporting economic operators in understanding the new requirements, thus helping them get ready to apply them. Data on all European MDs are collected in the [European Database on Medical Devices](#) (EUDAMED), including follow-up on all reported incidents and transparent information on ongoing trials. The overarching aim of these requirements is to ensure MDs are safe to use while at the same time fostering innovation so that patients gain access to novel care solutions. The new MDR also includes provisions intended to improve collaboration in Europe.

## REGULATORY CHANGE DRIVEN BY HEALTHCARE-RELATED SCANDALS INVOLVING MEDICAL DEVICES

These regulatory changes are the direct result of health scandals caused by defective medical devices that have severely affected people's health, as in the case of the breast implants manufactured by Poly Implant Prothèse (PIP). Instead of using medical-grade silicone, the PIP implants had been deliberately filled with industrial-grade silicone that did not meet the standards for implantable material. This large-scale fraud came to light in March 2010 during inspections by AFSSAPS, as ANSM was formerly known. The company did not meet the requirements governing certified procedures applicable to the production of implantable class III medical devices, the MDs that represent the greatest risk level for patients.

A total of 30,000 women received PIP breast implants – 9,000 of them after breast cancer surgery. Among all these women, some 3,000 breast implant ruptures were observed and 2,000 inflammatory reactions were reported. After a woman who had been fitted with a PIP implant died of lymphoma on 5 December 2011, France's director general for health (DGS, part of the French Ministry of Health) asked the French National Cancer Institute (INCa) to prepare recommendations for monitoring women at risk of developing lymphoma induced by the implants. French health minister Xavier Bertrand expanded the assignment after AFSSAPS reported a second adverse event involving a woman who had developed an adenocarcinoma of the breast in which a PIP implant had been fitted. Women with PIP implants who displayed abnormal clinical signs when consulting their doctor were told they had received a defective implant.

While this situation was bad enough for women who had received a defective implant during aesthetic surgery, it was a second blow to women who had undergone cancer surgery completed by breast reconstruction involving the insertion of PIP implants. It must be clearly understood that the reconstruction phase is not easy for women who have undergone cancer treatment, and some of them had considered it for several years before making their decision. They were not people who had light-heartedly hopped onto an operating table. Thanks to France's protective healthcare cost coverage system, patients who underwent post-cancer reconstructive surgery did not have to pay anything to have their PIP implants removed and new implants inserted, but they did have to pay any excess on the surgeons' fees. Furthermore, the traumatic nature of the experience resulted in some patients needing supportive psychological care, for which they did not receive any reimbursement.

From the moment the PIP scandal broke, the French [Ligue contre le cancer](#) (LCC, league against cancer) leapt to support the victims. It instituted civil proceedings and released emergency funding of 50,000 euros to provide material, psychological, and legal assistance to the victims. The French Supreme Court confirmed the conviction of the manufacturer of PIP implants in September 2018.

## THE LLC PRESENTS PATIENTS' POINT OF VIEW

The awareness of the toxic risks of these implantable medical devices provoked by such harrowing experiences can be expressed as a set of questions and answers

setting out the point of view of patients and patient organisations:

### Thinking back on these harrowing experiences resulting from the PIP scandal, what happened and what triggered the necessity of better regulation for medical devices?

The PIP affair caused serious harm to the women who received those breast implants and to civil society in general. This harm took several forms: lasting anxiety among women who have or used to have a PIP implant and among their relatives; a feeling of injustice at having been deceived when in a situation of great vulnerability; and a climate of mistrust and doubt towards the health system, which results in a loss of confidence in the health messages issued by public and medical authorities.

Drugs, which are a class of therapeutic products, have long had to fulfil a series of scientific requirements to obtain marketing authorisation. In addition, clinical

trials are required to demonstrate that drugs are both effective and safe before they can be placed on the market. According to the new regulation, medical devices – another class of therapeutic products – can now be certified only after clinical trials have been conducted. These trials must be approved by both an ethics committee and the competent national regulatory authority (ANSM in France). Nevertheless, the MDR still relies on certification by bodies, such as private certifying companies, whose impartiality vis-à-vis manufacturers is questionable. This is no substitute for marketing authorisation by a competent regulatory authority of the type required for drugs.

### Do patient representatives view the new MDR as a milestone?

The MDR is a major step forward in improving the safety of the care pathways followed by people who receive or use medical devices. To obtain certification, manufacturers are required to draw up investigation plans under which they conduct a scientific evaluation of the toxicity of the materials chosen for a device. Nevertheless, the requirements imposed by the MDR are less stringent than those for drugs, which is questionable.

As a representative of the people who use the health system, the LLC demands the introduction of proper European marketing authorisation for those medical devices that pose the greatest risk. We also want to see impartial, independent monitoring and certification bodies so that health disasters can be avoided.

### Does the new MDR address the concerns of the majority of patients?

The progressive implementation of the EUDAMED database will allow materiovigilance for medical devices by recording reports of adverse events identified by health-care professionals and the people directly affected. This

should help to identify weak safety signals early on and thus ensure that warnings can be issued and corrective action can be taken to safeguard device safety as quickly as possible.

**Some operators in the medical device sector claim that the complex nature of the new MDR is likely to slow down the pace of new developments in a kind of backlash against the tightening of regulatory requirements. Would you agree with this?**

It is certainly true that the new MDR will delay access to new medical devices because manufacturers now have to fund clinical trials for a longer period of time. However, patients' top priority is still to ensure safe care pathways, because when devices cause severe adverse events, the consequences for the people affected can sometimes be so severe that they include lasting after-effects and occasionally even disability.

All medical devices authorised in Europe will have to be recertified by May 2024. Given the large number of device dossiers, this deadline seems unrealistic, and there is a risk of patients being deprived of thousands of devices that are essential to their care. This risk of shortage should be analysed so that transitional measures can be introduced while recertification is in progress. Depriving patients of medical devices that they rely on in everyday life risks triggering another kind of public health crisis.

**Do you think that the key to guaranteeing safety is to strengthen regulations or should we be focusing instead on follow-up and continual auditing to ensure shortcomings are identified at an early stage?**

This MDR does increase patient safety, but it is the task of materiovigilance to undertake real-world monitoring and alert the authorities responsible for market surveillance, such as ANSM, to issues in the interests of providing long-term monitoring for medical devices on the same basis as medicines. Doing so would identify health scandals such as that caused by the PIP implants at an earlier stage and prevent them from affecting large numbers of people, who would in turn be spared the

distress of having to fight for their health and for their legal rights. Issuing proper marketing authorisation for medical devices could be considered at the European level as a way of increasing the safety of care pathways. Whereas drugs can be discontinued quite easily if they provoke an adverse reaction, removing an implantable medical device involves surgery that takes longer to implement, which not only causes stress, anxiety, and pain but also increases costs for the people affected.

## **MEDICAL DEVICE SAFETY: THE JOURNEY CONTINUES**

With any human activity, we must learn from our mistakes – a universal truth the medical device sector could not avoid. And even though the PIP breast implant scandal originated in France, it involved a German-based certifying body and impacted thousands of women in Europe, many of whom experienced this additional burden following breast cancer surgery. In its role as a defender of cancer patients, the LCC filed in the PIP

civil action for additional psychological care for patients, and the organisation continues to advocate on behalf of patients. The LCC acknowledges that the painful PIP experience has resulted in some progress, which is reflected in the new MDR and Swiss medical device regulations. Nevertheless, a few steps remain on this journey towards better medical device safety and thus patient safety.

# FEEDBACK FROM

swissethics

Schweizerische Vereinigung der Forschungsethikkommissionen  
Association suisse des Commissions d'éthique de la recherche  
Associazione svizzera delle Commissioni etiche della ricerca  
Swiss Association of Research Ethics Committees

## CHANGES TO THE MEDICAL DEVICE REGULATORY FRAMEWORK: LOOKING BACK – AND FORWARD

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The new regulatory framework for medical devices was long due. It aims to improve the safety and performance of medical devices and ensure a high level of protection for public health. Yet complying with the new legislation requires greater administrative effort and more resources, thus making compliance more expensive. In addition, there has been some uncertainty among researchers about how to correctly comply with the new legislation. This article looks back at the measures swissethics has taken to address some of these challenges and looks forward to additional measures to be implemented in the future.



## NEW REGULATORY FRAMEWORK FOR MEDICAL DEVICES: ADVANTAGES AND DISADVANTAGES

On the one hand, swissethics welcomed the implementation of the two new EU Regulations on medical devices ([Medical Device Regulation \(MDR\)](#) and [In Vitro Diagnostic Medical Devices Regulation \(IVDR\)](#)) as well as Switzerland's modification of its [Medical Devices Ordinance \(MedDO\)](#), its new [Ordinance on In Vitro Diagnostic Medical Devices \(IvDO\)](#), and its new [Ordinance on Clinical Trials with Medical Devices \(ClinO-MD\)](#). This legislation brings significant improvement to ensuring that only medical devices of high quality and with proven performance and safety are put on the market. In fact, there were numerous scandals due to defective and dangerous medical devices just a few years back, for example defective metal hip prostheses in Germany in 2015 and breast implants with unapproved silicone made by the company Poly Implant Prothèse (PIP) between 2001 and 2010 (see [DEEP DIVE](#)).

On the other hand, the new regulatory framework has come with additional burdens and costs. For medical device developers and manufacturers, the new regulatory framework translates into an obligation to prove performance and safety by conducting clinical trials for some classes of medical devices. This requires additional resources, thus increasing costs and resulting in significant administrative burdens. Indeed, the EU regulation has been criticised by the medical technology ([medtech](#)) industry as being too burdensome administratively, inhibiting innovation, and placing insufficient focus on technological advancement (see [VIEWS AND OPINIONS: SWISS MEDTECH](#)).

## LOOKING BACK: HOW DID SWISSETHICS RESPOND TO THE NEW FRAMEWORK?

### Harmonised process for reviewing and approving clinical trials

swissethics approached these challenges with one primary objective: to implement the new regulatory framework as simply and smoothly as possible for all stakeholders, including manufacturers, developers, researchers, and authorities. The main step taken toward this objective was to establish with Swissmedic a synchronised review and approval process for clinical trial submissions. This would make it possible to issue a single national decision letter that would include the requirements and conditions set by ethics committees and by Swissmedic.

In 2019, swissethics formed a core team and a working group to manage this first step. The core team, which consisted of three people, was responsible for creating a harmonised clinical trial approval process across the seven different ethics committees that was synchronised

with Swissmedic. The working group, composed of a representative from each ethics committee, pooled the experience of the individual committees, identified pitfalls, and tested and validated the process. The working group also ensured direct, two-way communication between the core team and individual ethics committees. This simple set-up allowed the two teams to be agile and flexible while at the same time remain focused and productive, not only as the process was being reviewed and improved but also throughout its final implementation and beyond. In early 2022, one year after implementation of the new synchronised process, the working group analysed the feedback from sponsors and researchers up to that point and then worked together with Swissmedic to further simplify the process based on the experience gathered by the ethics committees.

### New submission forms, templates, and guidance documents

The core team was also responsible creating a new, dedicated submission form in the [Business Administration System for Ethics Committees \(BASEC\)](#). One of the considerations that influenced the original design of the submission form was the future possibility of interchanging data with the [European Database on Medical Devices \(EUDAMED\)](#). This approach was not changed when the submission form was revised to accommodate performance studies on in vitro diagnostic medical devices (IVDs) in May 2022, despite the fact that one year earlier the Federal Council had decided to terminate negotiations of the EU Swiss Institutional Frame-

work Agreement. For researchers and sponsors, the core team also created and published templates for writing a [clinical investigation plan \(CIP\)](#) and a [clinical performance study plan \(CPSP\)](#) as well as guidance documents for [safety reporting](#) and for [notification of substantial amendments](#); the latter two documents were the result of a joint effort with Swissmedic. The CIP and CPSP templates were distributed to the clinical trial units (CTUs) and to Swissmedic for comments and corrections prior to publication. swissethics greatly appreciates the feedback from these institutions!

### Training on the new regulatory framework

After receiving input from swissethics and other stakeholders, the [Coordination Office for Human Research \(kofam\)](#) organised training sessions for ethics committees on the new regulatory framework. In addition, swissethics organised internal training sessions for the scientific and administrative secretariats of the ethics committees. These training sessions focused on the project flow in BASEC with its working instructions (first submission, amendments, safety), synchronisation with Swissmedic of the various review steps and final decisions, templates of decision letters, checklists, and other matters. The way the individual ethics committees informed and trained their members varied from eth-

ics committee to ethics committee, with some holding specific training sessions during their regular monthly meetings. The new regulatory framework was also a topic at the annual further education training events for members of ethics committees that take place each autumn (in Zurich, Lausanne, and Geneva).

swissethics, kofam, and Swissmedic agreed upon an approach for external communication to stakeholders. The goal was for the three institutions to align and distribute their communication in parallel, with each one focusing on its own role and responsibilities.

### Ongoing support for sponsors and researchers

The ethics committees and swissethics continue to support sponsors and researchers and address their questions through different channels. In most cases, this involves clarifying the applicable ordinance and risk categorisation of a research project. Another frequent question concerns which ordinance and risk category apply to companion diagnostic studies, with all imagin-

able case scenarios (e.g. one or two protocols with one or two independent sponsors for the investigational medicinal product (IMP) part and the IVD device part, a marketed/non-marketed IMP and an IVD device with CE marking/without CE marking, or an IMP tested in Switzerland and an IVD device partly done abroad or vice versa).

### LOOKING FORWARD: WHAT'S NEXT?

The ClinO-MD requires a clinical trial's sponsor to submit a final report with a summary in easily understandable terms to the ethics committee within one year of the end of the clinical trial. To promote transparency, swissethics is currently putting a system in place that will make these summaries in lay language available to the general public. The ethics committees and swissethics will also continue to collect feedback from

sponsors and researchers. Moreover, they will regularly assess whether the current review and approval process, templates, and guidance documents continue to fulfil their intended purpose and, if necessary, modify them. Despite all the changes the new regulatory framework has brought about, it has not changed swissethics' ultimate aim: to make Switzerland an even more attractive place for medical device development and research.



## **SWISSMEDIC'S EXPERIENCE WITH THE REGULATORY CHANGES FOR CLINICAL INVESTIGATIONS WITH MEDICAL DEVICES IMPLEMENTED IN 2021**

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Swissmedic, the Swiss Agency for Therapeutic Products, evaluates and approves clinical trials of medical devices in humans if the devices are not CE-marked or are used off-label. These activities are conducted by the Medical Devices Clinical Investigations division, which also ensures continuous surveillance while the clinical trials are in progress. In 2021, the European Medical Device Regulation introduced new requirements for clinical investigations with medical devices. In parallel, the new Swiss Ordinance on Clinical Trials with Medical Devices came into force, applying the European requirements in Switzerland. This legislation introduced major changes to medical device requirements and authorisation procedures. In this article, Swissmedic summarises its stakeholder-oriented response to these legislative changes. In addition, it refers to new information sheets, templates, and decisions trees that are available.

## PREPARING FOR THE ONSET OF NEW REQUIREMENTS FOR MEDICAL DEVICES

The European Medical Device Regulation (MDR), which included new product requirements, was first published in 2017. Due to the COVID-19 pandemic, its planned entry into force in 2020 was postponed for one year. However, well before the regulation came into force on 26 May 2021, manufacturers started aligning the development of new products to the new requirements. Across Europe, various manufacturers submitted MDR-based product documentation to competent authorities for the approval of clinical investigations. Even though the authorities in some European countries rejected such documentation if submitted before 26 May 2021, Swissmedic accepted MDR-based documents because it considered the MDR to cover all product

requirements of the previous regulation. In order to assist hospitals and small- and medium-sized manufacturers, Swissmedic published templates on its website for documents required by the MDR, notably for the voluminous template on compliance with standards and the general safety and performance requirements of the MDR. Collaborative preparations for MDR requirements were made at the European level. Swissmedic made its initial template available to the working group in charge of European documents; the template was also integrated into guidance document [MDCG 2021-08](#) and made available to all sponsors in the European region.

## IMPLEMENTING CHANGES TO THE AUTHORISATION PROCEDURE FOR MEDICAL DEVICES

Under the old regulatory framework, both parallel and sequential submissions to Swissmedic and to the responsible ethics committee were possible. Consequently, there was no possibility for reviewing institutions to coordinate efficiently with each other. Since the implementation of the new regulatory framework in 2021, procedures have been streamlined and cooperation between institutions has been strengthened in Switzerland. Parallel submission is now mandatory for all applications for risk category C clinical trials with medical devices, often referred to as pre-market clinical investigations. Cantonal ethics committees are responsible for delimiting research projects, so they should be contacted prior to parallel submission if there is any doubt about categorisation or other delimitation aspects.

In Switzerland, the right to be heard allows for communication between applicants and reviewing institutions, including the adaptation of study documents by the spon-

sor during the authorisation procedure. This has proven to be important for carrying out procedures efficiently. In addition, a simplified review procedure was introduced in 2021 and can be requested for certain investigations of non-invasive class I and class IIa devices. Swissmedic has published corresponding explanations in information sheets on clinical investigations with medical devices and performance studies with in vitro diagnostic medical devices (IVDs).

On 26 May 2022, principles that have applied to medical devices since 2021 also came into force for authorisation procedures for performance studies of IVDs. All authorisation procedures for pre-market clinical investigations of medical devices and interventional IVD studies now include parallel submission, an extensive right to be heard, and a simplified review of certain minimum risk research projects.

## RESPONDING TO THE 2021 CHANGES

Since Swissmedic accepted MDR-based documentation early on, the transition to MDR requirements in 2021 went smoothly, and surprisingly few questions arose. In the vast majority of cases, Swissmedic was able to respond to stakeholders' questions within one week. In 2022, Swissmedic approved 37 first-time applications for clinical trials and 100 changes requiring approval. Overall, Swissmedic checked a total of 143 notifiable changes, 106 annual safety reports, and 41 other safety reports from ongoing trials in Switzerland.

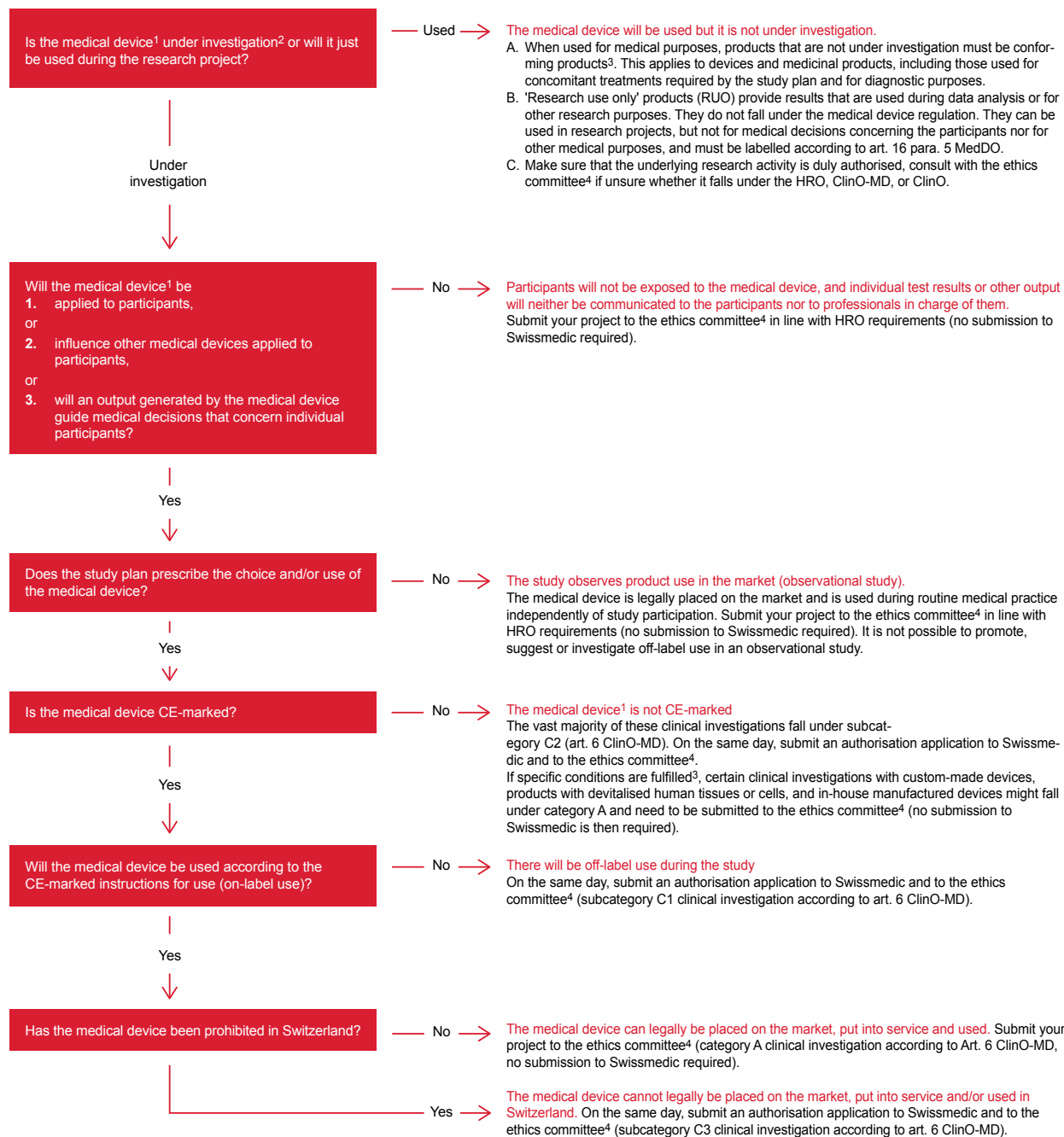
Despite a relatively smooth transition, sponsors kept sending questions to ethics committees and Swissmedic on the delimitation of research projects and asking whether specific projects would need Swissmedic's approval. Insecurities were possibly fostered by changes introduced with the Swiss Ordinance on Clinical Trials with Medical Devices (**ClinO-MD**). Notably, the ClinO-MD incorporates new EU definitions, which replace earlier terminology used in Switzerland that was based on the World Health Organization (WHO).

In 2021 and 2022, questions that arose were mostly related to the following issues:

- the distinction between interventional and non-interventional research
- products that can be placed on the market and used without a conformity mark
- research use only (RUO) products not intended to have a future medical use
- the location of laboratories for performance studies.

Some of these questions proved to be tricky due to the number of Swiss and European legal texts that needed to be consulted. Therefore, in 2022 Swissmedic, swiss-ethics, and the Federal Office of Public Health developed decision trees for applicants that are simple to use (see **Figure 1** and **Figure 2**). These decision trees, additional information on specific delimitation issues, and updates are now available online in Swissmedic's information sheets, which will be further refined based on feedback from sponsors.

Figure 1: Decision tree for authorisation applications related to clinical investigations with medical devices



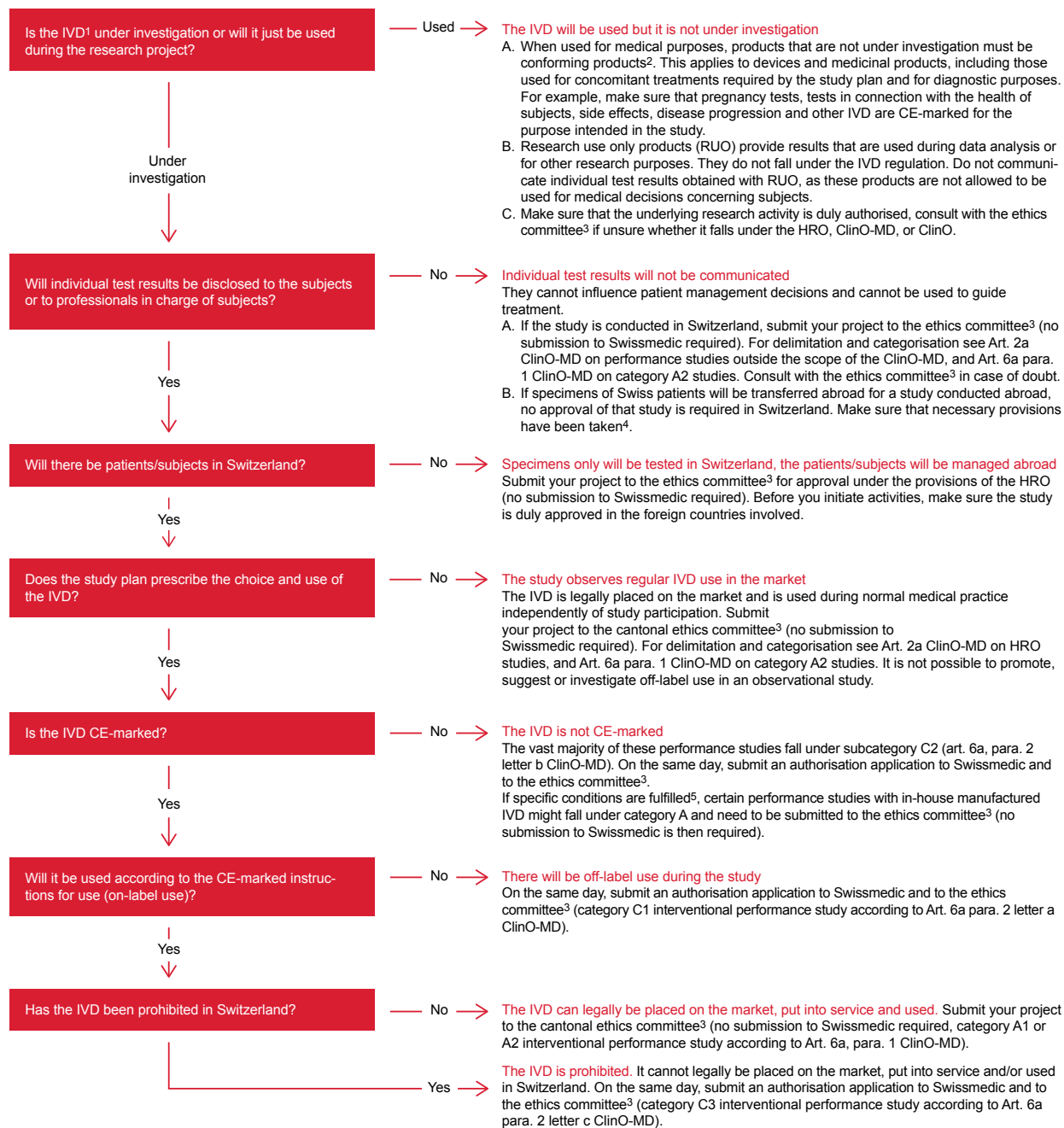
<sup>1</sup> The medical device can be a stand-alone product, or a product that is used as part of a system, including software (e.g. an app or an MRI sequence). Refer to art. 1 to 3 MedDO for definitions and exceptions. Consult the information sheet BW630\_30\_007e\_MB (Medical Device Software) and the European guidance document MDCG 2019-11 in order to determine whether a software is a medical device.

<sup>2</sup> Investigation for assessment of the safety or performance of the device.

<sup>3</sup> See Annex A7 of this information sheet for guidance on clinical investigations with custom made devices, with therapeutic products that contain devitalised human tissues or cells, or with certain medical devices manufactured and used in the same healthcare institution.

<sup>4</sup> The application for the clinical trial is submitted to the ethics committee responsible for the investigator. In a multicentric clinical trial the application is submitted to the lead ethics committee responsible for the coordinating investigator. The coordinating investigator is the individual with responsibility in Switzerland for coordinating the investigators responsible for the various trial sites in Switzerland. The list of ethics commissions that details the cantons for which they are responsible can be found here: [www.swissethics.ch/en/ethikkommissionen](http://www.swissethics.ch/en/ethikkommissionen).

Figure 2: Decision tree for authorisation applications related to performance studies with IVD



<sup>1</sup> The IVD can be used alone, or used as part of a system, including software (e.g. an app). Refer to the IVDO for definitions and exceptions. Consult information sheet BW630\_30\_007e\_MB (Medical Device Software) and the European guidance document MDCG 2019-11 in order to determine whether a software is an IVD.

<sup>2</sup> See annex A7 of this information sheet for guidance on interventional performance studies with IVD manufactured and used in the same healthcare institution.

<sup>3</sup> The application for the clinical trial is submitted to the ethics committee responsible for the investigator. In a multicentric clinical trial the application is submitted to the lead ethics committee responsible for the coordinating investigator. The coordinating investigator is the individual with responsibility in Switzerland for coordinating the investigators responsible for the various trial sites in Switzerland. The list of ethics commissions that details the cantons for which they are responsible can be found here: [www.swissethics.ch/en/ethikkommissionen](http://www.swissethics.ch/en/ethikkommissionen).

<sup>4</sup> You can find templates for material transfer agreements on the website of the [Swiss Biobanking Platform](http://www.swissbiobankingplatform.ch). On the website of [swissethics](http://www.swissethics.ch) you can find a template for a general consent for specimens taken in the clinical routine, and a template for a study specific informed consent form for specimens taken specifically for the study ([www.swissethics.ch](http://www.swissethics.ch) > Templates > Patient information and Declaration of consent). Please contact the cantonal ethics committee in case of doubt.

<sup>5</sup> See annex A7 of the information sheet for guidance on interventional performance studies with IVD manufactured and used in the same healthcare institution.

# VIEWS AND OPINIONS

## SWISS MEDTECH

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### CHALLENGES FACING SWITZERLAND'S MEDICAL TECHNOLOGY INDUSTRY FOLLOWING THE 2021 CHANGES TO MEDICAL DEVICE LEGISLATION

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In order to improve the safety of medical devices, the European Union and Switzerland made significant changes to their respective medical device legislation, which went into effect on 26 May 2021. The same day, Switzerland lost its privileged access to the European market. These legislative and political changes have impacted not only medical device manufacturers but also patients. This article discusses the challenges to the supply of medical devices in Switzerland and outlines what is needed to overcome them.



## INTRODUCTION OF THE MDR AND THE REVISED MEDDO

The [Medical Device Regulation](#) (MDR) is the legislation setting out the requirements that manufacturers must meet in order to sell medical devices in the European Union (EU). The MDR aims to further increase the safety of medical devices on the EU market. It has applied since 26 May 2021 and has had a major impact on all eco-

nomical actors, including manufacturers, importers, distributors, and, last but not least, patients. Manufacturers selling devices in Switzerland must also adhere to the Swiss [Medical Devices Ordinance](#) (MedDO), which has been completely revised to comply with the EU's MDR.

## SWITZERLAND'S THIRD COUNTRY STATUS

Switzerland was well aware that it would become a third country to the EU and lose its privileged market access if its mutual recognition agreement (MRA) with the EU was not updated prior to 26 May 2021. As an update became increasingly unlikely given the political climate between Switzerland and the EU, [Swiss Medtech](#) advised Swiss manufacturers and distributors as early as 2019 to prepare for third country status. A manufacturer from a third country must establish an authorised representative in the EU (EC REP), and in return the MedDO requires a Swiss authorised representative (CH REP) for all foreign manufacturers, which leads to additional administrative costs of around 2% of sales.

On the same day the MDR came into effect, the Federal Council broke off negotiations on the institutional agreement between Switzerland and the EU (InstA).

Within the hour, the EU Commission sent out a [notice to stakeholders](#) declaring all Swiss certificates invalid and requesting an EC REP immediately and without a transition period. This pinprick mainly affected the 54 Swiss manufacturers who held Swiss certificates, i.e. CE certificates issued by the Swiss Association for Quality and Management Systems (SQS), the Swiss notified body. Their medical devices were declared non-compliant for export to the EU, which is traditionally their most important trading partner and accounts for around 30% of their turnover. To regain conformity, these manufacturers must have their products recertified by a European notified body – a process that takes at least two years. Fortunately, Germany, the largest EU market, validated the Swiss certificates in January 2022, but the rest of the EU has not followed suit.

## THREE CHALLENGES FOR THE SUPPLY OF MEDICAL DEVICES

Today, with the hurdles established by the MedDO, a quarter of the foreign manufacturers that used to export their medical devices to Switzerland (1,200 out of 5,000 companies) have decided not to establish a CH REP and thus to stop trading. As a result, 15% of imported medical devices (60,000 of 400,000 products) are no longer available to Swiss patients. It is now up to importers and health professionals to urgently search for adequate replacements for the missing products.

The next two challenges are already emerging. According to a [survey](#) by MedTech Europe, the transition to the MDR will lead to a global portfolio reduction in CE-marked products by another 15%.<sup>1</sup> Even more alarming is that innovation is leaving Europe. The results of the survey show that a paradigm shift is currently taking

place. Half of the European manufacturers no longer give priority to the EU market for the initial approval of their new products. Instead, they have decided to apply for initial approval outside of Europe, for example at the US Food and Drug Administration (FDA). Especially in the case of forward-looking digital technologies, such as artificial intelligence and software as a medical device, the regulatory approach at the FDA is more advanced than in the European approval process. A novel medical device is first approved by the FDA and used by doctors in those parts of the world where FDA products are accepted. This leads to the paradoxical situation in which an innovation developed by a Swiss company with the help of Swiss doctors only becomes available to Swiss patients three to five years later than in other parts of the world where FDA approval is accepted.

### THE FUTURE OF SWISS REGULATION

In order to overcome the current supply challenge, Switzerland needs a stable relationship with the EU, a resolution of the outstanding institutional issues, and finally an update of the MRA between Switzerland and the EU. To overcome the emerging second and third supply challenges, Switzerland needs more room to manoeuvre by accepting medical devices from non-European regulatory

systems with comparable quality and safety standards. Such a step would not only significantly increase the attractiveness and innovative power of Swiss medical technology companies but also serve patients because they could immediately benefit from the most modern medical technologies.



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# VIEWS AND OPINIONS

## PATIENT ADVOCACY



### **PATIENT INPUT INTO MEDICAL DEVICE DEVELOPMENT: A MISSED OPPORTUNITY**

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The delivery of care to people who are patients has, beyond doubt, reached the digital age. This is never more striking than in the area of medical devices and in vitro diagnostic medical devices. Patients' standard of care has risen exponentially in light of the technological and innovative advances in the medical device field. Yet, in many instances, medical device development is undertaken without patient input. This article discusses why it is important to include patients' perspective in the process of developing medical devices. In addition, it addresses several related topics, such as the issue of access to medical devices and the need for transparency with regards to the data collected by medical devices. It also provides an example of a research project aimed to better understand and promote patient engagement in medical device development.

## MEDICAL DEVICE USERS: AN OVERLOOKED BUT VALUABLE SOURCE OF INPUT

The World Health Organization (WHO) reports an estimated two million different kinds of medical devices (MDs) on the world market, categorised into more than 7,000 generic device groups.<sup>1</sup> Currently, patients are either involved in the ideation phase or as beta testers, with little or no opportunity to provide input on how these devices will be used or how they are of value to their communities.<sup>2</sup> There is also a significant disconnect regarding the actual value of real-world evidence generated by the patients wearing the devices. Even though these patients have not developed the analytics to interpret the data, they still need to be consulted more often on the use or distribution of the data. Informed consent and protection has been put in place by legislation such as the EU's [General Data Protection Regulation](#) (GDPR); however, to be informed, one needs to be educated. There needs to be more true appreciation of and education on how and where data is valued for good and less-than-ideal situations.

Traditionally, the main driver of in vitro devices (IVDs) is to advance and improve healthcare practitioners' delivery of care. The complexity and rapid pace of technology

have been staggering, and this growth is reflected in the publication of the EU's 2017 [Medical Device Regulation](#) (MDR). However, there are a growing number of directly patient-facing devices: there are currently over 10 million digital health applications available, and by 2025 one in every three adults in America will wear a fitness tracker.<sup>3</sup> Some people find that including the patient's perspective will not improve devices' design, and they claim it only adds complexity and slows the agility of the development process. Thankfully, this mindset is receiving a solid challenge from patient groups and regulators. The development of medical devices should involve patients and the public throughout each stage. The inclusion of the patient's voice is essential to ensure that medical devices:

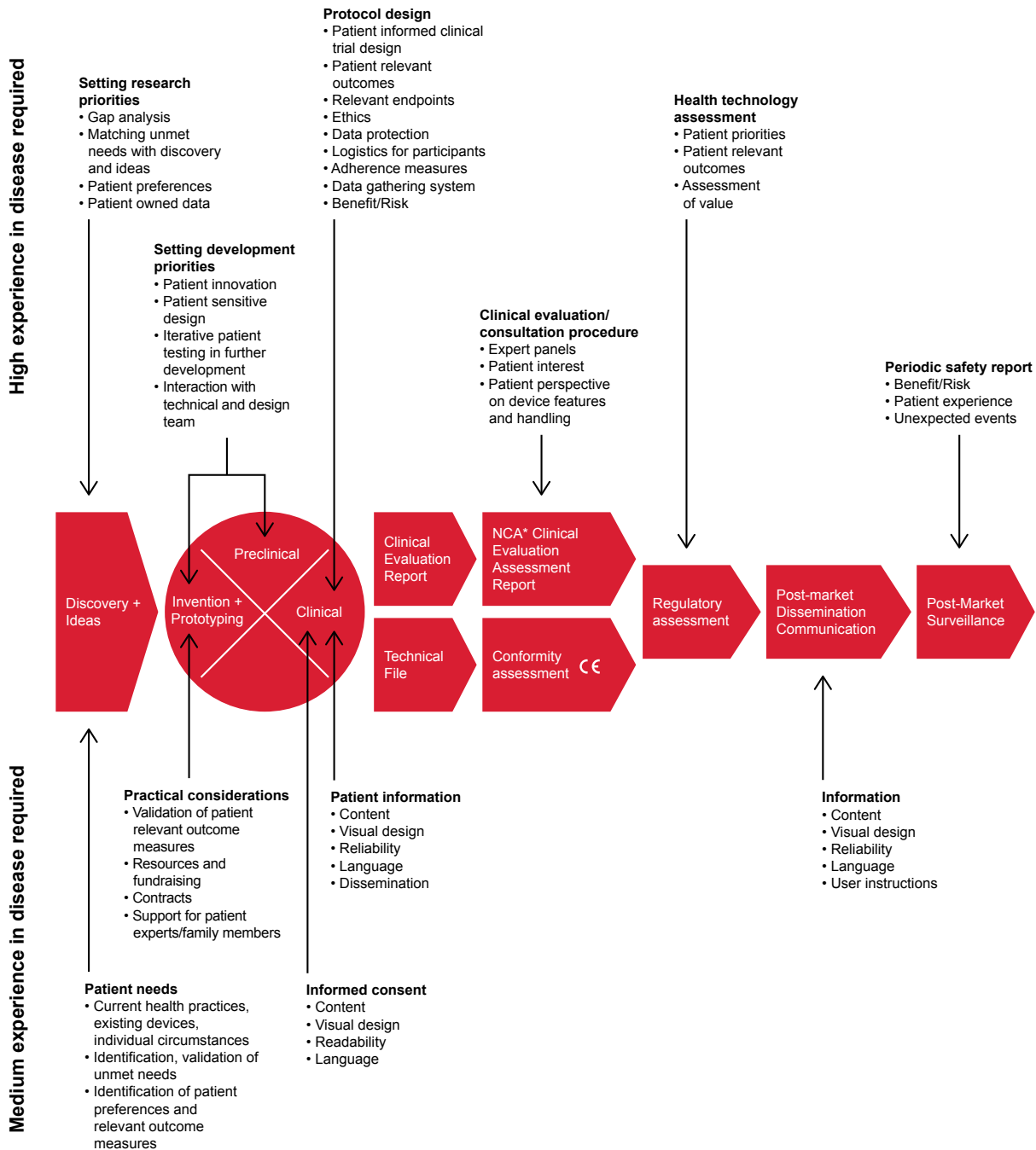
- address identified needs of patients and the public so they are useful and beneficial for those using the devices in the future and
- remain fit for purpose; a device without reference to user requirements cannot be fit for purpose in terms of ease of use, acceptability, affordability, and compatibility with other technologies.

## PATIENT ENGAGEMENT EFFORTS AT THE EUROPEAN LEVEL

In its factsheet for manufacturers of medical devices, the European Commission states, "The new Regulations create a robust, transparent, and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access for manufacturers."<sup>4</sup> Yet the practice needs to be more in sync with the European Medicines Agency (EMA) guidance regarding the inclusion of patients at all stages of therapeutic development.<sup>5</sup> Questions remain, however, about the value of including the patient's voice in the development of medical devices. Here it is essential to make

a distinction between devices that are directed towards healthcare professionals and those that directly interact with patients. There are efforts at differing stages to include the voice of people who are patients across the entire product life cycle. For instance, the European Patients' Academy on Therapeutic Innovation (EUPATI) has recently developed a [medical devices training module](#) in its course catalogue that shows how patients can be directly involved in medical device development (see **Figure 1** for EUPATI's roadmap of patient involvement).<sup>6</sup>

Figure 1: Concept roadmap of patient involvement in the different phases of medical device R&D



Source: Adapted from [EUPATI Open Classroom](#) (Lesson 3, Page 2, Figure 1 of the Medical Device Development, Lifecycle Management, New Technologies, Patient Involvement course);<sup>6</sup> licenced under [CC BY-NC-SA 4.0](#)

### MEDICAL DEVICES ARE BIG BUSINESS

The global market for medical devices is astronomical. In 2021, the global medical device market reached a value of nearly USD 488.98 billion and is likely to reach an impressive USD 718.92 billion by 2029.<sup>7</sup> To put that in context, it is greater than the combined gross domestic product (GDP) of 176 countries in the world.<sup>8</sup> This economic value, however, is coming at the cost of patients. And access to devices is a universal issue. Even in Switzerland, it is not 100% certain that every individual will be able to access life-changing medical devices in

the future. As cost and complexity increase, the market is looking to recoup R&D investment by allowing high-end access only. The global COVID-19 pandemic demonstrated that health systems are even more fragile than assumed. And because we have an ageing population, it is inevitable that there will be great costs for devices that can increase mobility and the quality of life. These costs will be covered only partially by insurance, and economic considerations often place constraints on patients' health decisions.

### INCREASING DATA TRANSPARENCY

It has become clear that at-home and personal devices play a central role in expanding the range of medical devices. Moreover, the device explosion has led to a vast array of data generated by each individual. This data has considerable value, but to whom? Primarily, its value is reaped by the organisations that have developed the digital tools designed for health interaction, including medical devices. Citizens and people who are patients need to be made aware of how and when their data can be used. And a more transparent system is needed for

demonstrating the value of data. The transparency of the systems is not only for financial gain but also for societal good. Data is a long-term asset, a fact that was recently highlighted by how public health epidemiological data can impact global health decisions. It is not only necessary that a person should actively own the data he or she generates, but there should also be a requirement to proactively demonstrate how and when a person's data is accessed and utilised.

**INCLUDING THE PATIENT’S PERSPECTIVE IN MEDICAL DEVICE DEVELOPMENT**

The inclusion of the patient’s voice is becoming much more embedded in therapeutic development, with a wealth of guidance available from the past twenty years. Both the US Food and Drug Administration (FDA) and the EMA have worked with patients to develop guidance on how to include patients in the decision-making process of therapeutic R&D.<sup>5,9</sup> This is not the case with medical devices. There is a need for a more balanced approach to including the patient’s voice in this most critical of health sectors since it safeguards the usability and safety of medical devices.<sup>10</sup> The FDA has started this patient engagement process and demands evidence of end-user engagement in health technology design when reviewing market pre-submissions.<sup>11</sup>

medical device design and development. As a first step, the patient empowerment consulting firm [Personal Pulse GmbH](#) teamed up with Dr Christine Jacob of the University of Applied Sciences and Arts Northwestern Switzerland (FHNW) and undertook a research project designed to address two important areas: (1) better understand the challenges and opportunities for including patients in the development of e-health technologies and (2) create a research-based, end-to-end, practical blueprint that can guide relevant stakeholders through how to successfully engage patients as co-creators in all human-centred design phases instead of viewing them as mere testers of pre-planned prototypes.<sup>2</sup> **Figure 2** depicts the first iteration of a blueprint that helps stakeholders understand how to include the voice of patients in all stages of human-centred development in e-health. These research findings can be applied throughout the medical device community.

In order to deliver impactful patient engagement, evidence-based research is required which delivers a systematic inclusion of patients at all stages of digital and

**Figure 2: Proposed blueprint for engaging patients as co-creators of e-health technologies**

	Specify context	Define user requirements	Produce design	Prototype	Deliver solution
<b>Maturity</b>	2.5 ★ average rating ★★★★☆ SD 0.8	2.7 ★ average rating ★★★★☆ SD 1.2	2.3 ★ average rating ★★★★☆ SD 0.9	3.3 ★ average rating ★★★★☆ SD 1.0	3.7 ★ average rating ★★★★☆ SD 0.8
<b>Sample considerations</b>	Diversify your sample to capture the different gaps and unmet needs	Involve patient experts in these phases as they require sophisticated skills and technical expertise		Diversify your sample again to ensure an inclusive design	
<b>Potential patient engagement approaches</b>	Online patient communities	Ideation and design thinking	A/B testing	Interactive diaries and checklists	Real-life testing or piloting
	Patient complaints or requests	Benchmark existing apps	Cocreate by embedding patients in all iteration rounds		Beta testing
	Workshops or focus groups	Moderated workshops or focus group to translate technical language to nontechnical users, and translate health care info to the technical teams			User analytics and platform metrics (hypercare)
	One-on-one interviews, if possible at their place			Lab or in-field testing (simulation)	



**Lifecycle management**

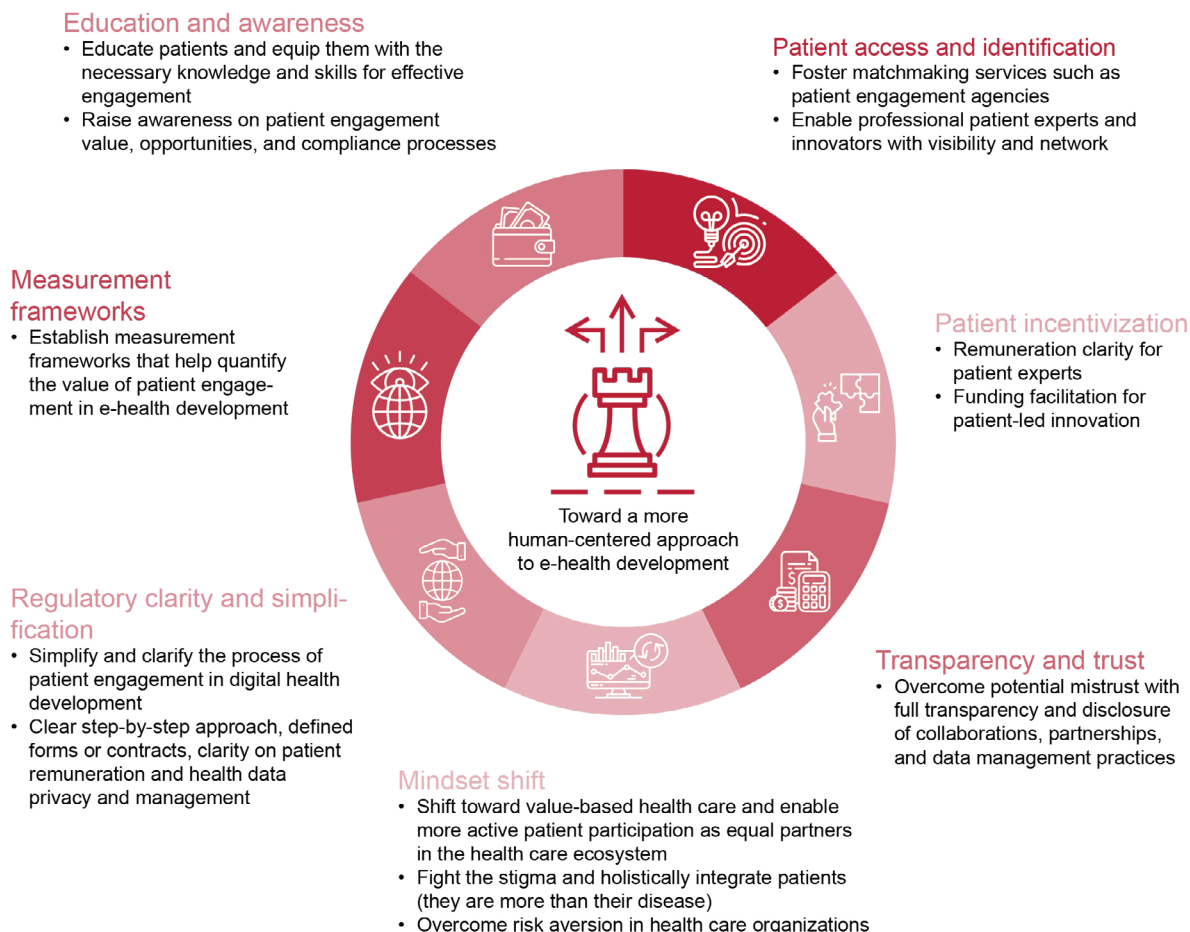
2.2 ★  
average rating  
★★★★☆  
SD 0.8

- Engage key opinion leaders and patient experts to periodically get their input
- Facilitate, promote, and monitor support line and email
- Monitor and respond to app store feedback
- Establish a drip email system to constantly seek feedback
- Transparently communicate about new iterations

Source: Adapted from [Jacob C, Bourke S, and Heuss S \(2022\), Figure 4<sup>2</sup>](#)

Figure 3 has been developed to help device manufacturers understand the practical, real-world implications and value of including patients at all stages of medical device development. It contains concrete examples for having a proactive discussion with stakeholders about including people who are patients.

**Figure 3: Practical implications of the From Testers to Cocreators study and its recommendations for more patient-driven e-health development**



Source: Adapted from Jacob C, Bourke S, and Heuss S (2022), Figure 5<sup>2</sup>

In conclusion, the development of medical devices – such as robotics, wearables, implants, and bionics – has turned the world of science fiction into reality. In order to ensure that medical devices serve the individual users as well as they are designed to do, we need to actively seek the opportunity to engage with people who are patients. Let’s not allow the value of patients to slip through our fingers.

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<sup>2</sup> Jacob C, Bourke S, and Heuss S (2022) From testers to cocreators – the value of and approaches to successful patient engagement in the development of ehealth solutions: Qualitative expert interview study. JMIR Human Factors 9(4):e41481. doi: [10.2196/41481](https://doi.org/10.2196/41481)

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<sup>4</sup> Directorate-General for Health and Food Safety (2020) Factsheet for manufacturers of medical devices. doi: [10.2873/66341](https://doi.org/10.2873/66341)

<sup>5</sup> European Medicines Agency (2022) Engagement framework: EMA and patients, consumers and their organisations. Accessed 2 Dec 2022: [https://www.ema.europa.eu/en/documents/other/engagement-framework-european-medicines-agency-patients-consumers-their-organisations\\_en.pdf](https://www.ema.europa.eu/en/documents/other/engagement-framework-european-medicines-agency-patients-consumers-their-organisations_en.pdf)

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# CASE STUDY

## PES-SLEEP PROJECT



### PATIENT INPUT INTO MEDICAL DEVICE DEVELOPMENT: A MISSED OPPORTUNITY

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[doi: 10.54920/SCTO.2023.RAWatch.8.6](https://doi.org/10.54920/SCTO.2023.RAWatch.8.6)

Since the revised [Medical Devices Ordinance \(MedDO\)](#) and the new [Ordinance on Clinical Trials with Medical Devices \(ClinO-MD\)](#) came into effect in Switzerland in May 2021, clinical investigators have encountered challenges in correctly categorising their research projects and identifying whether their projects pertain to the category of clinical studies with medical devices (governed by the ClinO-MD) or are considered human research other than clinical trials (governed by Chapter 2 of the [Human Research Ordinance \(HRO\)](#)). In this article, we discuss the PES-SLEEP project in order to illustrate a practical approach to this categorisation challenge between the lighter HRO regulatory framework and the more demanding ClinO-MD pathway. We also present the important points that were considered by the ethics committee for the canton of Vaud (EC Vaud) in order for the study to be approved as an HRO research project.

The [PES-SLEEP](#) project (registered title: Technical feasibility of measuring sleep physiological parameters using piezo-electric materials) is an ongoing exploratory observational study in humans. The study aims to collect information about the feasibility of recording signals that inform physiological sleep parameters by using a thin mat composed of pressure sensors. In this study, participants sleep on an experimental mat for one night, during which a standard examination for the measurement of sleep physiology (polysomnography (PSG)) is also recorded. Variables recorded with the mat are correlated (using machine learning techniques) with physiological parameters recorded with PSG (such as heart rate or breathing rate).

Professor Paul Franken (UNIL sponsor representative for the project) and Doctor Shanaz Diessler (principal investigator for the study) developed their research protocol with the help of the Clinical Research Centre (CRC) Lausanne and submitted it to the EC Vaud as an HRO project ([Chapter 2](#), human research other than clinical trials), first with healthy participants (without sleep complaints) and then with participants with sleep complaints (after amending the research protocol).

During the study's protocol development phase in October 2021, the CRC Lausanne, which is in charge of coordinating the Regulatory Affairs Platform of the Swiss Clinical Trial Organisation (SCTO), had the opportunity to co-organise the annual roundtable meeting between Swissmedic, swissethics, and the SCTO. At this meeting, the criteria for considering a technical object to be a medical device were discussed, and some illustrative case studies were challenged. It appeared that Swissmedic's main criterion was related to the purpose of a technical object within a study. In the PES-SLEEP study, the mat with pressure sensors is not a standard product but was developed by Professor Franken's research team specifically for the study. In addition, it was used in a proof of concept stage with, first and foremost, a feasibility objective. The research project is not being conducted in order to assess the safety or the performance of the set-up as a medical device designed for sleep recordings for diagnosis purposes. Instead, the research team aims to collect information about the feasibility of recording any useful signals (in terms of sleep physiology) by using such pressure sensors in a "mat" configuration. These are the reasons why the project falls within the scope of an observational prospective study involving humans and is thus governed by the HRO instead of the ClinO-MD. Moreover, the PES-SLEEP study

does not expose participants to any particular personal safety risk. The pressure sensors in the mat are not in direct contact with participants since the sensors are placed on the underside of the mat, which is beneath the bed sheet, and they operate without external voltage or current source; only discomfort related to sleeping with electrodes (for PSG) may be felt by participants. The study thus falls within risk category A since the planned measures entail only minimal risks and burden for participants. The research team estimated that recording twenty participants would allow for a sufficiently robust association analysis in this observational study.

The PES-SLEEP study was first designed for healthy participants without sleep complaints, who were recruited by the Center for Integrative Genomics (CIG) at the University of Lausanne (UNIL). The study received approval from the EC Vaud in January 2022. After the inclusion of 6 out of 20 healthy participants, the data recorded were of good quality, and the initial analysis demonstrated that signals recorded with the mat could give highly accurate estimates of heart and breathing rates, thus forming a solid starting basis. Given these promising results, the research team wanted to study a more representative sample of the population (with more variability) by recording not only good sleepers (i.e. healthy participants) but also people with poor sleep (i.e. participants with sleep complaints). Therefore, an amendment to the PES-SLEEP project was submitted to the EC Vaud in July 2022 to include 50 participants with sleep complaints, to be recruited by a second recruitment site: the Center for Investigation and Research in Sleep (CIRS) at Lausanne University Hospital (CHUV). These participants were referred to the CIRS because they had a priori disturbed sleep; they were not selected for the study on the basis of a diagnosis for a specific sleep disorder. The measures with the experimental mat as well as the sleep analysis (PSG) is conducted by UNIL. Data from the experimental device will not be used for diagnosis and will not impact participants' health in any way, which is why the project still qualifies as an observational study. The amended protocol received the approval of the EC Vaud in September 2022.

In conclusion, the PES-SLEEP study demonstrates that it is possible to carry out the proof of concept phase of a device within the framework of an observational study insofar the device in the study is used to verify the feasibility of measurements of the experimental device and not to verify its safety or its performance for the purpose of making a diagnosis.

# REGULATORY NEWS, EVENTS, AND PUBLICATIONS

## SWITZERLAND

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### Federal Council

#### NEWS

- **JUNE 2023**

**Federal Council opens consultation on ERI Dispatch for 2025–2028**

The Federal Council has opened the consultation on the Dispatch on Education, Research and Innovation (ERI Dispatch) for 2025–2028. This is the first time an ERI Dispatch has been submitted for consultation. The consultation will run until 24 September 2023; the Federal Council is expected to pass the 2025–2028 ERI Dispatch to the Swiss Parliament at the end of February 2024.

Source: [Federal Council website \(Press releases\)](#)

#### NEWS

- **JUNE 2023**

**New federal data protection legislation will enter into force in September 2023**

After a complete overhaul of Swiss data protection law, the new Federal Act on Data Protection (nFADP) will enter into force in September 2023. It will improve the processing of personal data and will grant Swiss citizens new rights. The nFADP should make it possible to maintain the free flow of data within the European Union and thus avoid a loss of competitiveness for Swiss entities.

Source: [Federal Council website \(Data protection\)](#)

### Swiss Clinical Trial Organisation (SCTO)

#### EVENT

- **JUNE 2023**

**SCTO Symposium: Clinical research in the age of digital health**

The SCTO held its annual symposium in June on the topic of clinical research in the age of digital health. The event included presentations about real-life examples of digital health applications and discussions on legal and ethical aspects that have to be taken into consideration.

Source: [SCTO website \(SCTO Symposium 2023\)](#)

#### PUBLICATION

- **SEPTEMBER 2022**

**Core competencies in clinical research**

The journal *Swiss Medical Weekly* published an article written by the SCTO's Education Platform describing the work it did on developing the [Clinical Research Core Competencies \(CRCC\) Framework](#). The article aims to make researchers, research teams, and those responsible for training aware that a framework for such competencies exists. The CRCC Framework is recognised by all Swiss universities and Clinical Trial Units (CTUs) in the SCTO's network.

Source: [Swiss Medical Weekly](#)

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## Swissmedic

### NEWS

- **JUNE 2023**

#### Public consultation on ICH Good Clinical Practice Guideline E6(R3)

Swissmedic has launched a public consultation on the Good Clinical Practice (GCP) Guideline E6(R3) of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human use (ICH). Stakeholders in Switzerland have the until 26 September 2023 to comment on the draft of ICH Guideline E6(R3).

Source: [Swissmedic website \(General communications\)](#)

### PUBLICATION

- **JUNE 2023**

#### Swissmedic's 2022 annual report

Switzerland's Federal Council has approved Swissmedic's annual report for 2022. The report includes information on Swissmedic's performance and financial overviews as well as informative facts and figures related to Swissmedic's various activities over the past 20 years.

Source: [Swissmedic website \(General communications\)](#)

### PUBLICATION

- **MAY 2023**

#### Report on Swissmedic's medical device inspections in hospitals

In accordance with its legally defined mandate, Swissmedic monitors the reprocessing, maintenance, and vigilance of medical devices in hospitals. The 2021/2022 annual report of Swissmedic's hospital inspections is now available online.

Source: [Swissmedic website \(Medical devices\)](#)

### NEWS

- **JANUARY 2023**

#### Updated guidance and forms for reporting SAEs and device deficiencies

The European guidance and the form for tabular summary reporting of severe adverse events (SAEs) and device deficiencies have been updated. Swissmedic has also adapted its forms and tables accordingly.

Source: [Swissmedic website \(Announcements\)](#)

### NEWS

- **JANUARY 2023**

#### Simplified application reviews and adapted fees for clinical trials with medical devices and performance studies with IVDs

Swissmedic has published information about the possibility of simplified reviews for authorisation applications and adapted fees for clinical investigations of medical devices and performance studies of in vitro diagnostic medical devices (IVDs).

Source: [Swissmedic website \(Announcements\)](#)

### PUBLICATION

- **DECEMBER 2022**

#### Position paper on decentralised clinical trials with medicinal products

An updated version of Swissmedic's and swissethics' joint position paper on decentralised clinical trials (DCTs) with medicinal products in Switzerland is now available (version 2.0 dated 15 December 2022).

Source: [Swissmedic website \(Clinical trials on medicinal products\)](#)

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## **Swiss National Science Foundation (SNSF)**

### **NEWS**

- **JUNE 2023**

#### **SNSF announces a more forward-looking organisational structure**

The SNSF has devised a new organisational structure for itself so that it can continue to fulfil its tasks efficiently and professionally in the future. The SNSF's revised statutes with this more contemporary and adaptable structure have been approved by the Federal Council and will be effective at the beginning of 2024.

Source: [SNSF website \(What's new\)](#)

## **EUROPE**

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## **EU Commission**

### **NEWS**

- **JANUARY 2023**

#### **Proposed amendment to the EU's MDR and IVDR**

On Friday, 6 January 2023, the European Commission published a proposal for an amendment to the EU's Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR). The amendment aims to prevent the threat of supply bottlenecks and interruptions after the end of the transition period.

Source: [European Commission](#)

## **INTERNATIONAL**

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## **US Food and Drug Administration (FDA)**

### **PUBLICATION**

- **MAY 2023**

#### **US guidance document on decentralised clinical trials**

The FDA distributed a guidance document for comment purposes only entitled Decentralized Clinical Trials for Drugs, Biological Products, and Devices. Comments can be submitted online until 1 August 2023.

Source: [FDA website](#)

## PUBLICATIONS

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- **Griessbach A et al. (2022 April 4)** The concept of general consent in Switzerland and the implementation at the University Hospital Zurich: A cross-sectional study. *Swiss Medical Weekly* 152:w30159.

doi: [10.4414/SMW.2022.w30159](https://doi.org/10.4414/SMW.2022.w30159)

In this article, the relationship between demographic and medical factors in patients' decisions to give general consent at the University Hospital Zurich was investigated.

- **World Health Assembly (2022 May 27)** Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination. WHA75.8 resolution (agenda item 16.2). Accessed 23 Jan. 2023.

Source: [https://apps.who.int/gb/ebwha/pdf\\_files/WHA75/A75\\_R8-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_R8-en.pdf)

The World Health Organization (WHO) published the draft text of the clinical trial resolution on 24 May 2022, which was debated at the 2022 World Health Assembly. The resolution's overall aim is to improve the coordination, design, conduct, and reporting of clinical trials worldwide. The resolution was adopted, and the WHO will work with the technical working group to formulate guidance on best practices for clinical trials.

- **HMA, EC, and EMA (2022 Dec 13)** Recommendation paper on decentralised elements in clinical trials (version 01). Accessed 23 Jan 2023.

Source: [https://health.ec.europa.eu/system/files/2022-12/mp\\_decentralised\\_elements\\_clinical-trials\\_rec\\_en.pdf](https://health.ec.europa.eu/system/files/2022-12/mp_decentralised_elements_clinical-trials_rec_en.pdf)

A joint recommendation paper on decentralised elements in clinical trials was drafted by the Heads of Medicines Agencies' (HMA) Clinical Trials Coordination Group (CTCG), the European Commission's (EC) Expert Group on Clinical Trials (CTEG), and the European Medicines Agency's (EMA) Good Clinical Practice Inspectors Working Group (GCPIWG). The paper addresses the roles and responsibilities of the sponsor and investigator, electronic informed consent, investigational medicinal product (IMP) delivery, trial-related procedures at home, data management, and monitoring in a decentralised clinical trial setting.

- **Shabani M and Yilmaz S (2022)** Lawfulness in secondary use of health data: Interplay between three regulatory frameworks of GDPR, DGA & EHDS. *Technology and Regulation* 2022:128–134.

doi: [10.26116/techreg.2022.013](https://doi.org/10.26116/techreg.2022.013)

In recent years, the secondary uses of health data for clinical, research, and policymaking purposes have become even more important in view of the availability of health-related data. Processing health data requires adopting adequate legal and ethical protections in order to ensure that the rights of data subjects have been respected while also facilitating responsible access to data. In this paper, the authors aim to shed light on the interplay between the existing and emerging relevant European regulatory frameworks related to data processing, including the General Data Protection Regulation (GDPR), the upcoming Data Governance Act (DGA), and the legislative proposal for the European Health Data Space (EHDS).

## ABBREVIATIONS

<b>AFSSAPS</b>	Agence française de sécurité sanitaire des produits de santé (precursor to French National Agency for Medicines and Health Products Safety)	<b>InstA</b>	institutional agreement between Switzerland and the EU
<b>ANSM</b>	French National Agency for Medicines and Health Products Safety	<b>IVD</b>	in vitro diagnostic medical device
<b>BASEC</b>	Business Administration System for Ethics Committees	<b>IvDO</b>	Ordinance on In Vitro Diagnostic Medical Devices
<b>CE</b>	Conformité Européenne	<b>IVDR</b>	In Vitro Diagnostic Medical Devices Regulation (EU)
<b>CH REP</b>	authorised representative in Switzerland	<b>kofam</b>	Coordination Office for Human Research
<b>CHUV</b>	Lausanne University Hospital	<b>LCC</b>	Ligue contre le cancer (league against cancer, France)
<b>CIG</b>	Center for Integrative Genomics	<b>MD</b>	medical device
<b>CIP</b>	clinical investigation plan	<b>MDR</b>	Medical Device Regulation (EU)
<b>CIRS</b>	Center for Investigation and Research in Sleep	<b>MedDO</b>	Medical Devices Ordinance
<b>ClinO-MD</b>	Ordinance on Clinical Trials with Medical Devices	<b>medtech</b>	medical technology
<b>CPSP</b>	clinical performance study plan	<b>MRA</b>	mutual recognition agreement
<b>CRC</b>	Clinical Research Centre	<b>nFADP</b>	new Federal Act on Data Protection
<b>CRCC</b>	clinical research core competencies	<b>PIP</b>	Poly Implant Prothèse
<b>CTCG</b>	Clinical Trials Coordination Group	<b>PSG</b>	polysomnography
<b>CTEG</b>	Expert Group on Clinical Trials (European Commission)	<b>RA</b>	regulatory affairs
<b>CTU</b>	clinical trial unit	<b>RUO</b>	research use only
<b>DCT</b>	decentralised clinical trial	<b>SAE</b>	serious adverse event
<b>DGA</b>	Data Governance Act (EU)	<b>SCTO</b>	Swiss Clinical Trial Organisation
<b>EC</b>	European Commission	<b>SNSF</b>	Swiss National Science Foundation
<b>EC REP</b>	authorised representative in the EU	<b>SQS</b>	Swiss Association for Quality and Management Systems
<b>EC Vaud</b>	ethics committee for the canton of Vaud	<b>swissethics</b>	Swiss Association of Research Ethics Committees
<b>EHDS</b>	European Health Data Space	<b>Swissmedic</b>	Swiss Agency for Therapeutic Products
<b>EMA</b>	European Medicines Agency	<b>UNIL</b>	University of Lausanne
<b>ERI Dispatch</b>	Dispatch on Education, Research and Innovation	<b>WHO</b>	World Health Organization
<b>EU</b>	European Union		
<b>EUDAMED</b>	European Database on Medical Devices		
<b>EUPATI</b>	European Patients' Academy on Therapeutic Innovation		
<b>FDA</b>	US Food and Drug Administration		
<b>FHNW</b>	University of Applied Sciences and Arts Northwestern Switzerland		
<b>GCP</b>	good clinical practice		
<b>GCPIWG</b>	Good Clinical Practice Inspectors Working Group (EMA)		
<b>GDP</b>	gross domestic product		
<b>GDPR</b>	General Data Protection Regulation (EU)		
<b>HMA</b>	Heads of Medicines Agencies		
<b>HRO</b>	Human Research Ordinance		
<b>ICH</b>	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use		
<b>IMP</b>	investigational medicinal product		
<b>INCa</b>	National Cancer Institute (France)		

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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 regulatory authorities in Switzerland, Europe, and the USA; ICH and WHO; major Swiss academic organisations and health associations; and professional associations.
- Additionally, we review major clinical research journals.

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