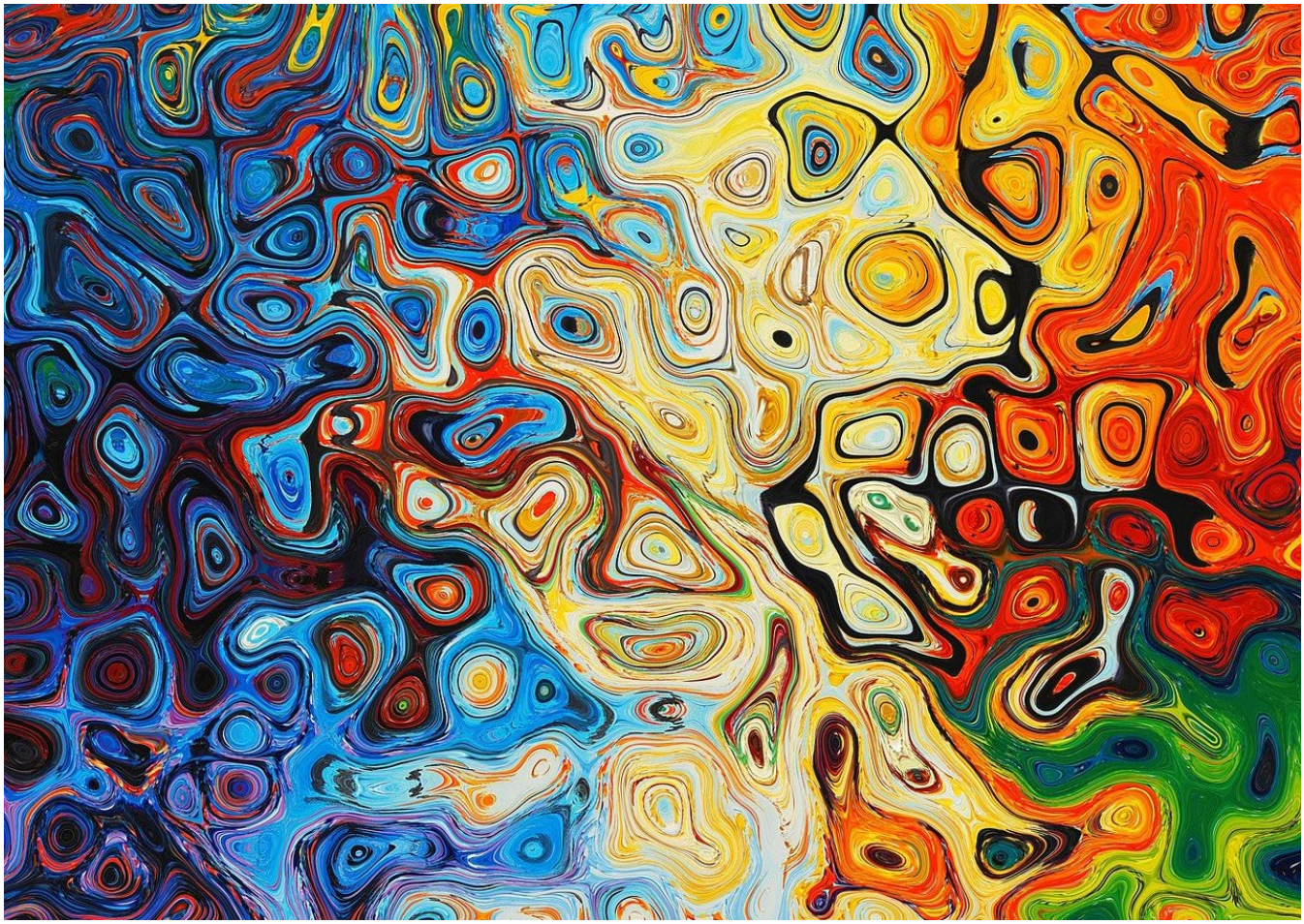

Project “New innovation models in Switzerland”
Sector brief: Medical technologies

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Disclaimer

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Executive summary

Literature review

Medical devices comprise a broad range of products that rely on advanced knowledge of disease mechanisms, clinical practice, and engineering. Innovation therefore requires coordinated advances in product design, medical procedures, and understanding of human physiology, involving diverse stakeholders such as firms, clinicians, regulators, research institutions, investors, and patients. Owing to this interdisciplinary nature, collaboration is central to Medtech innovation, enabling access to complementary capabilities, particularly for digital and service-oriented innovation. While hardware remains essential, Medtech is increasingly shaped by digitalisation, data-driven solutions, and service models, including smart devices, advanced manufacturing, automation, AI-enabled diagnostics, and digitally supported therapies.

Digital transformation is widely identified as a key force in Medtech, encompassing electronic health records, connected devices, data analytics, and eHealth services. In Switzerland, however, digitalisation remains comparatively slow due to fragmented health IT infrastructures, limited interoperability, unclear rules on secondary data use, high implementation costs, workflow misalignment, and persistent concerns about data privacy and trust. The limited uptake of electronic patient records exemplifies these challenges.

Sustainability has gained importance in Medtech, but sector-specific constraints limit circularity. Single-use devices are often favoured for safety reasons, while reuse requires sterilisation and organisational capabilities that are not always available. Regulation plays a decisive role in shaping innovation. European frameworks such as the MDR and IVDR strengthen patient safety but increase development costs, extend approval timelines, and disproportionately burden SMEs. Regulatory uncertainty and complex approval processes slow the introduction of high-risk innovations. Similar effects are observed under Swiss regulations, which are closely aligned with EU rules.

Summary of survey findings

The survey reveals substantial heterogeneity in innovation activities, regulatory exposure, and collaboration patterns across product risk classes. Innovation is widespread, but its form and intensity differ systematically depending on regulatory environment, technological exposure, and internal capabilities.

Product and process innovation patterns vary across segments. Process innovation has gained importance, while radical innovation remains rare overall. Firms in higher and highest risk classes introduce innovations less frequently than those in lower or non-classified categories. R&D activity levels remained broadly stable: higher-risk firms increasingly add R&D contracts to their in-house R&D, while firms without risk classification reduce internal R&D.

Perceived competitive pressures are similar across risk classes, but technological dynamism is seen as weaker in higher-risk segments, suggesting that stringent regulation dampens the innovation impact of technological change. Digitalisation follows a similar pattern: hardware improvements are central across all firms, while AI and big data are more relevant for low- and medium-risk firms than for Medtech players in the higher/highest-risk segment.

Sustainability-related innovation has increased overall but is least common among higher-risk firms, reflecting trade-offs between contamination risks and environmental goals. Regulatory exposure rises sharply with risk class, with higher-risk firms reporting stronger impacts on innovation costs, uncertainty, and outputs. Collaboration is most prevalent among higher-risk firms, which rely heavily on clinicians and regulatory bodies, while academic partners are particularly important for firms without risk-classified products.

Summary of Delphi interviews

The Delphi interviews depict a dynamic but increasingly constrained Swiss Medtech innovation ecosystem. Participants consistently highlighted digitalisation, regulatory burden, collaboration challenges, financing gaps, and emerging sustainability expectations as dominant influences.

Innovation is largely incremental and application-oriented, with start-ups concentrating most radical innovation. Digital transformation – spanning AI-supported diagnostics, automated manufacturing, and new service models – is seen as critical but constrained by limited access to patient data, strict privacy rules, and fragmented e-health infrastructures. Participants stressed the need for centralized, standardized, and secure data platforms and clearer rules for secondary data use.

Regulation emerged as the most significant constraint. MDR requirements are viewed as costly, slow, and poorly suited to iterative innovation, while Swiss procedures are described as opaque and heavily dependent on EU frameworks. Proposed reforms include regulatory sandboxes, fast-track approval pathways, and more risk-based regulation.

Sustainability is relevant but remains secondary to regulatory compliance. Collaboration is widely recognised as essential, yet SMEs face difficulties identifying partners, navigating academic collaboration, and accessing international expertise. Financing gaps – particularly for clinical phases and scaling – represent a major bottleneck, with respondents calling for more transparent, flexible, and industry-oriented funding instruments. Persistent shortages of specialised talent further constrain innovation capacity.

1 Introduction

In autumn 2022, the State Secretariat for Education, Research and Innovation SERI commissioned a study to explore the decline in R&D-performing companies and trends in the innovation activity of Swiss companies by means of six hearings with representatives from industry sectors. This study revealed several factors that pose major challenges to companies' innovation activities (Barjak et al., 2023). These include, above all:

1. Growing centricity of consumers and generally clients in processes of innovation,
2. Widespread digitalisation of innovative products and services,
3. Marked demands for considering sustainability in innovation projects,
4. Increasing influence of regulations,
5. Transformation of the competitive environment (e.g., geographically, new entrants from technology industries, disruptive start-ups, etc.).

Most importantly the first study made clear that the conditions and contexts of innovation are to some degree sector-specific, and that a “one-size-fits-all” approach is neither suitable to understanding corporate innovation activities nor from a policy perspective appropriate to support them. Following this preliminary study, the National Council’s Committee for Science, Education and Culture submitted postulate 24.3009 ‘Declining innovation activities of Swiss companies. Identify the causes and remove the obstacles’, which was accepted by the National Council on 30.05.2024. The Federal Council was instructed by this postulate to analyse in detail the causes of the decline in innovation activities by companies in Switzerland and to provide answers as to how the obstacles in the innovation process can be removed.

SERI commissioned this research project to inform the Federal Council’s reply to this postulate. The project is dedicated to new sectoral innovation models and their consequences for innovation policies. Against this background, four key areas of adjustment were defined to better understand the new innovation models, identify potential weaknesses in the current (regulatory) policy framework and, if necessary, propose recommendations for Swiss innovation policy: 1) Data-related practices and needs in corporate innovation activities, 2) sustainability-related innovation activities and drivers and bottlenecks of such innovations, 3) collaboration practices and needs, and 4) regulations. The project has addressed these four themes and analysed the current situation and recent changes in six selected sectors. It thus enables in-depth and more specific analyses that are not possible on the basis of innovation surveys of the entire Swiss economy. The selected sectors are: 1) Medical technologies (Medtech), 2) finance (banking, insurance, & fintech), 3) pharmaceuticals, 4) information and communication technologies, 5) MEM (metals, electronics & machine industries), and 6) food and beverages.

This sector brief is part of the larger project.[1] It presents the findings of the project for the medical technologies (Medtech) sector, differentiating the survey data further for four segments and summarising the results of the Delphi interviews conducted with companies and industry experts.

[1] Barjak, F., Heimsch, F., Cornet, B., Foray, D., Wörter, M. & Schenckery, A. (2026). *New innovation models in Switzerland. Report on behalf of the Swiss State Secretariat for Education, Research and Innovation (SERI).*

2 Literature review

2.1 Specifics of medical device innovation

Medical devices have been defined as “all equipment used in the provision of medical care that does not primarily function through biological or chemical means” (MacNeill et al., 2020, p. 2088). They cover a broad range of products used in healthcare, from low-complexity, cheap and often single-use disposable products like syringes and catheters to high-complexity instruments with long lifespans like medical imaging instruments or dental chairs (MacNeill et al., 2020).

Medical devices are in several senses special products which influences also the characteristics of medical device innovations. The functionality and design of a medical device depends on robust knowledge of both, the nature of disease and the comparative clinical performance of available therapeutic solutions (Barberá-Tomás & Consoli, 2012). Medical products cannot be separated from the health services in which they are used and the medical manufacturing economy and the medical service economy are effectively one (Metcalfe et al., 2005).

Medical device innovation requires the advancement of knowledge in three areas (Metcalfe et al., 2005; Morlacchi & Nelson, 2012):

(1) The design and engineering of medical artefacts,
(2) the medical procedures (of physicians, medical staff, healthcare organisations in general) which use the artefact, and
(3) diseases and body functions in general.

These different areas of expertise required for innovation are reflected in the involvement of a variety of stakeholders in healthcare innovations (MedTech Europe, 2020): established companies, start-ups, research institutes, customers (care providers, patients), regulatory/policy makers, “indirect” players, for example investors in startups, care providers, suppliers and manufacturers. If parts of the diverse knowledge under (2) or (3) above are missing or uncertain, medical device engineering might resort to *hybridization*, understood as “making ‘available’ different operational principles within a single device” (Barberá-Tomás & Consoli, 2012, p. 933). Even though medical devices still consist essentially of hardware, the frontier of Medtech innovation is described as increasingly digital, software-driven, data-intensive, and service-oriented. Swiss Medtech identified five types of innovation drivers for the Swiss medical technology sector in its most recent survey (Swiss Medtech & Helbling, 2024):

(1) *Product innovation*: smart devices (wearables, hearables, implantables, etc.), material innovations, substitution technologies (e.g. new sensors for non-invasive and invasive continuous measurement of body data, etc.), data recording, and individualisation (e.g. of prostheses, implants, electronic tablets).
(2) *New manufacturing processes*: Digitalisation of industrial production, automation and robotisation, substitution technologies such as 3D printing, miniaturisation, etc.
(3) *Diagnostics*: Service automation, patient data processing (e.g. big data, AI), personalised medicine, augmented/virtual reality applications (e.g. simulation of procedures), improvement of the human-machine interface.
(4) *Therapy*: Automation and robotisation to reduce the workload on staff, automation of interpretation and decision-making based on diagnostic values, etc.
(5) *Healthcare*: patient behaviour for prevention, satisfying patients' information needs, telemedicine, branding of healthcare brands

Since health innovations must minimise risks to patients and medical staff as far as possible and require complex and expensive approval procedures, radical innovations have become relatively rare, and the majority of incremental innovations now builds on established solu-

tions (Knape et al., 2020). The decision about investing in medical device innovation is further complicated, as not only the expected health effects are relevant for this decision, but also its further impact on users/consumers, on individual organizations (e.g., hospitals) and the health system regarding service quality, costs, and ethical aspects (Guerra-Bretaña & Flórez-Rendón, 2018). MedTech Europe (2020, p. 11) estimated the global Medtech R&D intensity (investment divided by sales) at 8% and lower that in pharmaceuticals or semiconductors. However, the report also points to a different path to innovation by transferring technologies from other sectors such as automotive and aeronautics into medical technology innovations.

2.2 Data and digital transformation

The 2020 MedTech Europe Reflection Paper on "Innovation in Medical Technologies" pointed to four key application areas of digitalisation in healthcare:

- Electronic health records (EHRs),
- Connecting medical devices with information systems (e.g., the Internet of Things (IoT) or wireless technologies),
- Utilisation of large amounts of data generated by medical devices (e.g., through AI), and
- "eHealth" understood as new digital methods for providing care.

According to the most recent Swiss Medtech Report, Swiss Medtech companies perceive the digitalisation, automatization and robotisation of production processes as the most relevant innovation topic they are confronted with (Swiss Medtech & Helbling, 2024). One third of the respondents has used AI in connection with product innovations and another third plans to do so in the future (ibid., p. 62). High priority was also attributed to product innovations such as smart devices, sensor-based data recording and analysis, and material innovation, as well as the increasing desire of patients to obtain information about illnesses, healthy living, therapies, etc. – except for material innovation, all these topics are strongly related to data and the digital capabilities of products. In a workshop conducted as a precursor to this project, the participating experts lamented that digitalisation processes in the Swiss Medtech industry are (too) slow (Barjak et al., 2023). In the European context it has been found that framework conditions and regulations in particular are a strong inhibitor of digital innovation (European Commission. Directorate-General for Research and Innovation et al., 2025).

The digital transformation of the Medtech industry is to large degree embedded in the digital transformation of health systems which in most countries meets several challenges. Electronic health records (EHR) serve as an example to illustrate this. Several problems have led to limited success of many EHR initiatives (Kruse et al., 2016; Slawomirski et al., 2023; Tsai et al., 2020):

- Problems of interoperability and fragmentation of health data,
- legal barriers (e.g., unclear rules about secondary use, research access, data sharing across borders) and fragmented data governance,
- high upfront installation costs (e.g. for IT, integration, training) and incompatibility with reimbursement models,
- poor usability and fit of solutions with established workflows,
- and last but not least concerns about data privacy and security, and lack of trust among patients.

The Swiss experience illustrates many of these general problems, plus a few Swiss-specific twists and suggests that Switzerland is not a front runner in the digital transformation of its health system. The federal structure implies that Switzerland adopted a federal law on electronic patient dossiers (Elektronisches Patientendossier Gesetz EPDG) to create a framework for EHR while the implementation, however, is organized through regional actors and coordinated by the cantons, which introduced multiple decentralisation challenges (De Pietro

& Francetic, 2018). EHR uptake has been a lot slower than originally expected, both because of delayed adoption by healthcare providers as well as reluctance among patients and concerns about privacy and control of health data (Daniore et al., 2024). The Swiss Federal Council therefore in November 2025 launched a new initiative for an EHR to replace the EPD.[2]

2.3 Sustainability innovations

Sustainability and the consideration of the environmental and social dimensions and impacts of economic activities in addition to the economic dimension has also gained importance in the Medtech sector – according to the most recent Swiss Medtech survey three quarters of Swiss Medtech companies have addressed the issue of sustainability in one way or another (Swiss Medtech & Helbling, 2024).

Previous studies point to several different influences on sustainability innovations in the Medtech sector:

- The use of medical products may generate special challenges for sustainability: as the reuse of medical devices may come with a higher perceived contamination risk, single-use devices have been trending (Hoveling et al., 2024; MacNeill et al., 2020; Sousa et al., 2021). They have been found to come with higher environmental costs than multi-use devices (MacNeill et al., 2020; Sousa et al., 2021). The reuse of medical devices requires the users to have sterilization equipment, or, alternatively, to pass on the device to an external service provider for sterilization and reprocessing (Sousa et al., 2021). Hoveling et al. (2024) point to (perceived) safety risks (e.g. infection and decontamination concerns), challenges with collecting and sorting devices as barriers to increasing circular economy practices in the medical device industry.
- Regulation exerts a strong impact on sustainability-oriented innovations among medical device producers as well. Weak, i.e. unclear, inconsistent, or changing, regulations within or between countries can hinder companies innovation activities to make their products more sustainable (Auer & Jarmai, 2018). High technical, regulatory, and ethical complexity of products and services, lack of knowledge and experience with regard to sustainable approaches, and the interdisciplinary nature of healthcare innovations make it challenging to implement sustainability aspects (Auer & Jarmai, 2018; Barbero et al., 2017; Hoveling et al., 2024).
- Sustainable or green public procurement for healthcare raises the importance of sustainable medical technologies and opens up business opportunities for companies able to satisfy this need (Barbero et al., 2017; Oruezabala & Rico, 2012). It has been shown that above all SMEs react to public procurement that includes environmental selection criteria by developing more environmentally-friendly products (Krieger & Zipperer, 2022).
- Not only customer requirements, but also the rules and requirements of partners or internal ethical and responsible thinking of owners and managers may trigger responsible innovation activities (Auer & Jarmai, 2018). Tactics like forced obsolescence to prevent the reuse or reprocessing of medical devices in order to increase sales might also hinder the diffusion of more sustainable practices (Hennein et al., 2022; MacNeill et al., 2020).
- Last but not least, higher innovation costs expected from sustainable innovations might also hinder their implementation (Auer & Jarmai, 2018).

[2] https://www.edi.admin.ch/de/bundesrat-beschliesst-neuausrichtung-elektronisches-gesundheitsdossier-e-gd-loest-epd-ab

2.4 Regulation

Relevant regulations

The main regulations governing the market entry and use of medical devices in Europe are the Medical Device Regulation (MDR) and the In-Vitro Diagnostic Medical Device Regulation (IVDR) which were both issued in 2017 by the European (IVDR, 2017; MDR, 2017). While these new regulations aim above all for increasing health protection and considerably raise the requirements for products (e.g., clinical safety, performance) and producers, the increase of innovation is not their primary objective (Barth et al., 2021).

The regulations require that most medical devices brought to market bear the Conformité Européenne (CE) mark – with few exceptions under certain conditions, e.g., for a hospital's own medical device developments (MDR, Art. 5), or for investigational devices used for the purpose of a clinical investigation (MDR, Art. 20). The regulations not only govern market-conformity and pre-clinical and clinical testing and evaluation (premarket), regulatory product evaluation during market entry, but also post-market monitoring and reporting requirements on product and manufacturing processes (Guerra-Bretaña & Flórez-Rendón, 2018; Kearney & McDermott, 2023). They specify in detail the terminology, processes and accompanying documents that must be provided to obtain and keep the CE mark.

Classifying products into risk groups serves to reconcile the regulatory requirements with the potential health consequences of product use. The European regulation differentiates between non-invasive, invasive, active and implantable medical devices to classify their risks (MDR, 2017). The U.S. Food and Drug Administration (FDA) distinguishes between low-risk, moderate-risk and high-risk medical devices (Stern, 2017).

Switzerland has its own Medical Devices Ordinance (Medizinprodukteverordnung, MepV, SR 812.213). The Swiss regulation not only refers to the European regulation with regard to product groups (Art. 15), but in several other regards. Based on the unilateral recognition of the CE mark by Switzerland, the approval of a new product by European authorities and according to the European regulations is a lot more attractive for companies than the approval for the Swiss market only. Swissmedic stresses that its focus with regard to medical devices is mainly on market surveillance and designating and monitoring the CE conformity assessment bodies and the drafting of requirements in the form of technical standards.3

Another regulation that matters for the medical device industry is the Swiss Federal Law on Health Insurance (Bundesgesetz über die Krankenversicherung, KVG, SR 832.10) that regulates the reimbursement of health services. Switzerland uses a prospective payment system (PPS), the Swiss Diagnosis Related Groups (SwissDRG) for the reimbursement of hospital services. Such prospective payment systems provide incentives for health service providers to apply the least resource-intensive treatments (Maresova et al., 2020). According to the expert workshop in the Medtech sector conducted prior to this study, the strong focus of hospitals on cost effectiveness, revenues, and profits rather than on finding the best treatments, e.g., by engaging in clinical trials, does not incentivize innovation (Barjak et al., 2023). If a treatment gets cheaper, the insurance tariff goes down. Hospitals therefore do not have a strong interest in better treatments, if they drive costs up.

Approval of medical devices

The approval process of medical devices is complex, as the health-related added value of a medical technology innovation is difficult to measure: double-blind experiments might be impossible or unethical in clinical trials, e.g. when devices have multiple uses and indications or are embedded into more complex procedures (Ciani et al., 2016; Guerra-Bretaña & Flórez-Rendón, 2018). The outcome of these and impact on patients' health depends on

[3] https://www.swissmedic.ch/swissmedic/en/home/medical-devices/regulation-of-medical-devices.html

what end-users, i.e. health professionals, do with the obtained results and how well patients follow prescribed treatments. Moreover, the performance of medical technology innovation depends on organizational settings and competences of the users. This creates an additional burden for evaluating a medical device innovation: if users lack full competences, which is not unlikely, for instance in case of rapid technological progress, short product life cycles and fluid uses and competence requirements (Ciani et al., 2016), the medical value of a medical device innovation might be underestimated. In sum, the relationship between a medical device innovation and patient health is not easy to measure.

The approval of high-risk medical device innovations is burdened by two types of uncertainty: first, technological uncertainty about how a medical device works and how the regulator knows that it works; second, content and format uncertainty about the requirements and criteria for new device approvals (Stern, 2017). As Stern (2017) has shown, above all this content and format uncertainty lengthens the approval process of high-risk device innovations by the US FDA by 7.2 months (more than a third of total approval time). This additional time adds costs in the range of 7% of all R&D costs during the approval process and it affects above all pioneers. The additional approval time goes down when the regulator has collected experiences with a new device and been able to issue and publish regulatory guidelines. Along similar lines, one of the main challenges for the clinical evaluation of medical devices under the new European MDR has been described as understanding the requirements and information needed in the certification of a medical device (Kearney & McDermott, 2023).

According to Guerra-Bretaña and Flórez-Rendón (2018) the relationships between medical device developers and regulators are crucial for successful innovation. They suggested that companies and regulators partner early to find solutions for reducing uncertainty in the approval process and regulatory agencies should develop “regulatory science” according to new technology development.

Impact of regulations

Regulations may support or hinder companies to innovate. On the one hand, setting rules and, as is the case with the European MDR/IVDR, harmonizing them provides clarity and makes it easier and more attractive for companies to develop medical products. On the other hand, regulations might create new requirements and processes for the development of medical devices and their curation during their lifecycles which is expected to be negative for medical device innovations (Barth et al., 2021). Through administrative complexity, inconsistent implementation, and slow or unpredictable procedures regulations might harm innovation – such effects have been attributed to a lack of accountability across layers of governance in case interviews on the European MDR/IVDR (European Commission. Directorate-General for Research and Innovation et al., 2025). Structured dialogue with notified bodies could reduce this problem (ibid.).

Medical device regulations have been said to focus on static efficiency, i.e. optimal healthcare provision (patient safety and health protection) for the lowest costs, and not consider sufficiently dynamic efficiency and innovation (Barth et al., 2021; Ciani et al., 2016). Incentives for improving medical devices and services constantly are lacking in such a situation. While costs of healthcare provision are growing, there is a tendency to judge healthcare innovations primarily with regard to their effects on costs and less so with regard to their value added (Nusser & Lindner, 2010).

Empirical studies in the US have found that longer and more costly processes of having high-risk medical devices approved affects above all small firms, which are then less likely to employ a pioneer strategy and more likely to act as innovation followers (Stern, 2017). Similar effects are expected for the new European regulations, MDR/IVDR (Barth et al., 2021; Ladd, 2023; Maresova et al., 2020): above all SMEs will be affected as some of their limited

resources will be absorbed by working on clinical tests and validations, providing the detailed information for product approval, and ensuring post-market surveillance and vigilance (i.e., the monitoring and risk assessment of unwanted events). Reduced access to venture capital might also be one of the negative impacts of the regulatory uncertainty on start-ups (European Commission. Directorate-General for Research and Innovation et al., 2025).

Impacts of MDR/IVDR in Switzerland. Since May 2021 Switzerland has "third country" status in relation to the EU market. Medical technology products from Switzerland therefore do not have a preferred market access to EU markets anymore and they are confronted with higher hurdles, above all acquiring the CE mark and having an authorised representative in the EU market (Swiss Medtech & Helbling, 2022). To cope with the effects of MDR/IVDR, companies recruited additional personnel and made internal adjustments. The recruitment of personnel with expertise in regulatory affairs and with other competencies required for doing the premarket, market launch and post-market testing, analyses, and surveillance has been difficult and Swiss Medtech companies and their suppliers have struggled with finding adequately qualified staff. The increase of personnel resources is estimated at about 3% in the 2022 and 2024 Swiss Medtech Surveys and companies have stated to reduce personnel involved in ongoing R&D projects to cope with the new regulations (Swiss Medtech & Helbling, 2022, 2024). The introduction of MDR/IVDR increased the development costs of a medical product in Switzerland considerably, by 12% according to the 2022 Swiss Medtech Survey and by 28% according to the 2024 survey. Product costs were estimated to grow by 6% (2022) and 13% (2024) (Swiss Medtech & Helbling, 2022, 2024).

Almost half of Swiss medical technology companies also receive approval from the US Food and Drug Administration (FDA), and a political initiative for the market approval of FDA-certified products in the Swiss market was passed by parliament in 2022 and is currently being implemented.

2.5 Innovation collaboration

Medical device innovation requires knowledge from different areas of science, covering different medical and biomedical sciences as well as engineering. Collaboration is perceived as a driver of Medtech innovation (MedTech Europe, 2020). Case studies have shown that innovation requires close relations and interactions between a broad set of actors, including firms, medical faculties, hospitals, and physicians: for the Intra-Ocular Lens (IOL) (Metcalfe et al., 2005), the Transcatheter Aortic Valve Implantation (TAVI) (Mikhailova, 2022), or the cochlear implant (Blume, 1995). Analysing digital service innovation in four Swiss medical technology companies, Stähle (2020) finds that external collaboration helps to mobilize complementary capabilities which are not available internally.

Firms are central players in health innovation systems, as they connect the different actors and their knowledge and orchestrate the innovation process creating their own networks of suppliers and health organisations competing for business (Metcalfe et al., 2005). Rival firms build their own local concentrations of innovation resources (ibid., p. 1301) and Medtech innovation on the one hand depends on open innovation in networks and ecosystems. On the other hand, for different players in the health sector, e.g. hospitals, strict requirements with regard to IT and data security complicate the participation in open innovation regimes (Knape et al., 2020).

We are not aware of studies that evaluated innovation collaboration in the Swiss Medtech industry or in the health sector in general. During the precursory workshop for this study, several comments were made that suggest that innovation collaborations encounter challenges: The number of organisations and initiatives in the Swiss research and innovation system has grown, and companies are confronted with a jungle of institutions. Above all SMEs struggle with finding partners. Competences in the ETH sector or in large research organisations tend to be hidden from the outside because they are very advanced and current

research topics do not reveal what else the organizations know. Numerous public and private initiatives (such as innovation parks, innovation centres, innovation hubs, etc.) add to the non-transparent jungle of players. Art. 15 funded-organizations like sitem aim to bridge the gap between universities and firms, e.g., by offering an open innovation platform, but companies are more interested in direct scouting than in the more abstract ecosystem (Barjak et al., 2023). Universities and research organisations are fragmented and a national strategy or platform to make their knowledge usable in a productive manner is lacking. Therefore, companies struggle to find the entry or starting point, above all SMEs. Big players, e.g., large pharmaceuticals, have better access to the universities, and they can absorb all the university/ETH capacities for technological work. SMEs find closed doors and they struggle both with the “translation” of their needs to the scientists and with the adaption of the scientific results to their needs. Whereas large companies already have processes and networks to deal with these complexities, SMEs are often overwhelmed and struggle to identify the right partners and collaboration formats (Barjak et al., 2023).

3 Sector-specific survey results

3.1 Data basis and method

The survey data in this section draws on a dataset generated through an online survey of Swiss Medtech companies in Dec. 2024-March 2025. Questions asked about the most recent time frame 2021-23, following the Swiss Innovation Survey and European Community Innovation Survey practice of collecting innovation data for a three-year time-period. In order to detect changes over time, questions were also asked about the previous period in 2020 and earlier. No precise time frame was specified, as it was assumed that events that occurred longer ago would be subject to memory errors and that any precision would only be apparent.

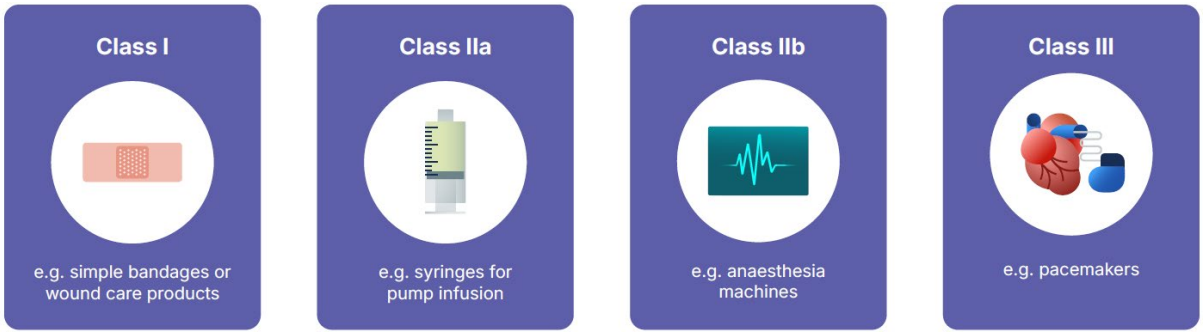
A sampling frame of 543 UIDs (VAT numbers) was obtained from the Swiss Federal Office of Statistics (FOS) and Swiss Medtech Association membership. 307 (56%) of the addresses were for micro enterprises with up to 9 employees, 178 (33%) for small enterprises with 10-49 employees. Mid-size (47, 9%) and large (11, 2%) companies were the minority.

The responses to the survey identified 47 of the 543 Medtech UIDs as outside the research population, e.g. not companies but government offices or not-for-profit organizations, inexistent (e.g. companies that closed down), or several UIDs for one entity. From the resulting 496 Medtech companies 128 responded to the questions, 29 rejected to participate, 35 could not be reached (non-functioning mail/postal addresses), and 304 did not respond. The Medtech response rate is 25.8%.

In addition to the FOS NOGA code, which is allocated based on main economic activity of a company, we asked the respondents in the survey to self-assess their industry using different levels of the NOGA system. We then calculated fractional sector memberships per company, i.e. reducing the Medtech weight for a company that self-classified belonging to further industries and raising it for companies which self-classified as Medtech but belonged to a different main industry according to the FOS classification. This re-weighting resulted in 134.8 Medtech companies. Only the companies among these 134.8 which had self-classified also as Medtech companies saw a further question which asked them for the risk classes of their products (according to MDR), differentiating between four classes and companies with products outside the risk classification (Figure 1). As companies can produce multiple products, multiple responses were permitted. Out of 134.8 companies 42 companies did not answer the question on the risk class, either because they did not answer the questions and dropped out, or because they did not self-classify as Medtech. Of the responding 92.8 companies 20.9 classified as risk class not applicable, 40 (43%) as low risk class I, 37.8 (41%)

as medium risk class IIa, 22.5 (24%) as higher risk class IIb, and 15.8 (17%) as highest risk class III. We added up the two subsets of higher and highest risk classes for the analysis.

Figure 1. Medical device risk classes



Source: MedTech Europe (2024, p. 7)

Below we show the survey results differentiating the companies by risk classes. The results are only valid for the companies in the dataset as innovative companies are overrepresented.

3.2 Results

3.2.1 Innovation activities in the Medtech sector by segment

Innovation outputs

Product innovations. The patterns with regard to product innovations by Medtech companies are not very clearcut (Figure 2). While in the first period more companies in the medium and higher risk classes introduced new or improved goods than in the lower risk classes, this is not the case in 2021-23. Moreover, fewer companies in the higher and highest risk classes introduced new or improved services than in the other segments in both periods. The share of product innovators among companies for which risk classes are not applicable is higher than among higher and the highest risk classes. Companies producing invasive, active, and/or implantable medical devices seem to innovate less often, with regard to goods and services, than companies producing less demanding goods and services.

In terms of the degree of novelty, we distinguish between two types:

- radical or new to market product innovations and
- incremental or new to the firm product innovations

While four out of five Medtech companies are incremental innovators, less than half are radical innovators (Figure 3). While all companies among those that do not sell products within a risk class introduced incremental innovations, less than one out of five of these companies introduced radical innovations. For the other risk classes, the share of radical innovators is higher at around 50% while the share of incremental innovators is at 75-85%.

Figure 2. Product innovations in the Medtech sector by segment

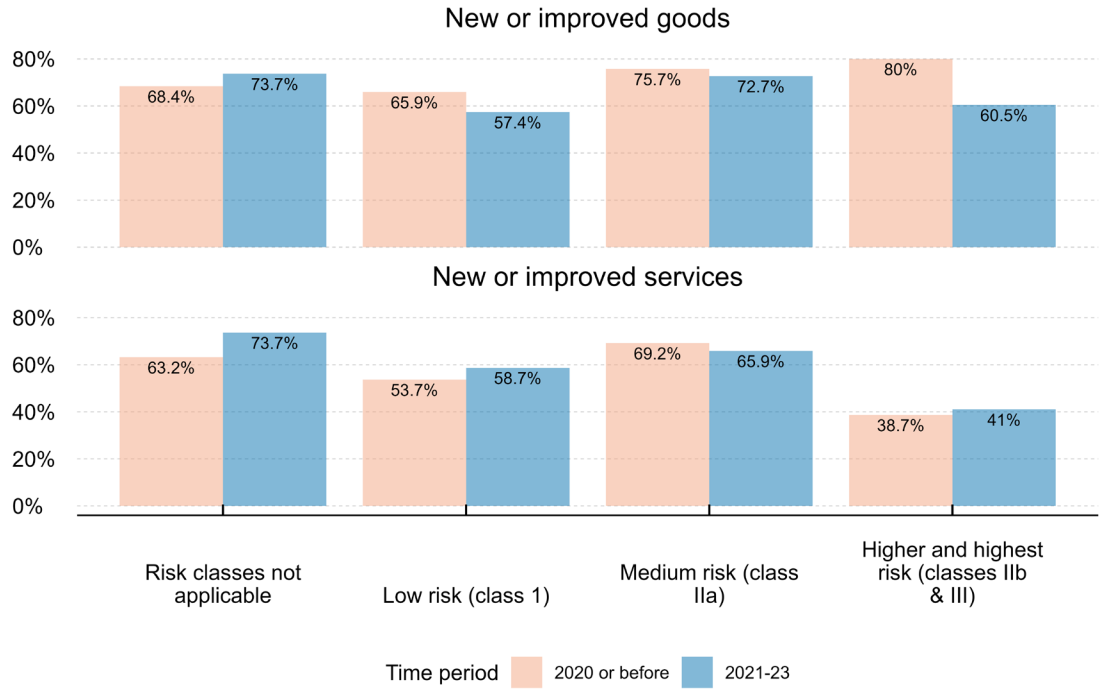
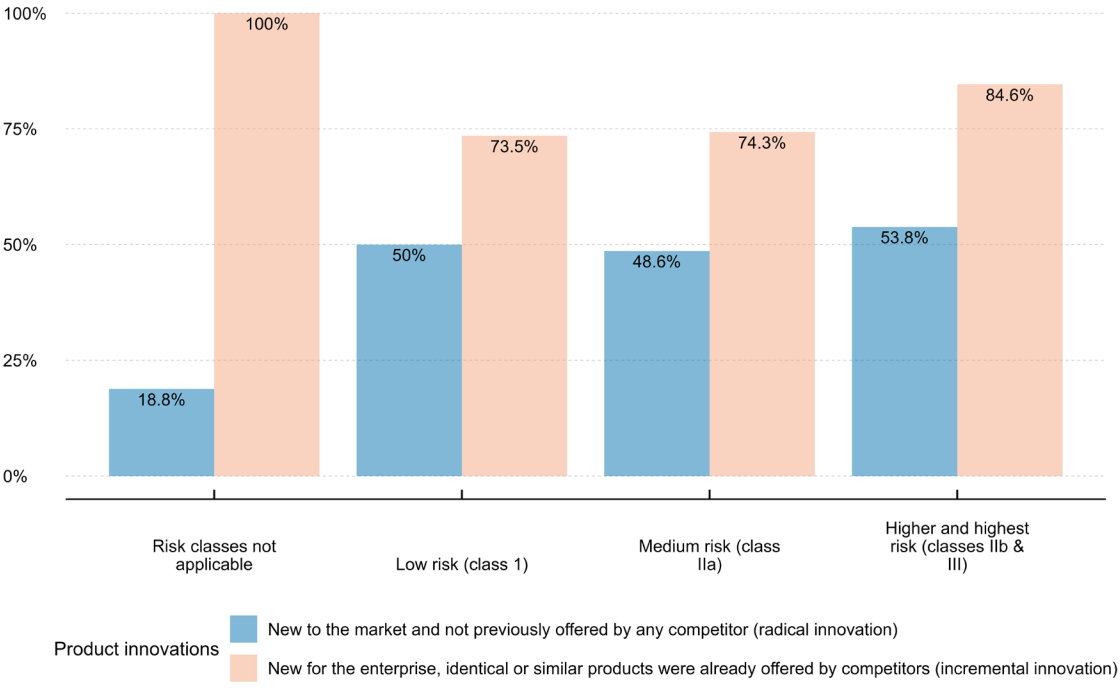


Figure 3. Radical and incremental product innovations in the Medtech sector by segment (in %)



Process innovations. The importance of process innovations has grown 2021-23 compared to 2020 and before independent of the risk class (Figure 4). In the second period 2021-23 the share of process innovators is slightly smaller in the higher and highest risk classes than in the other risk classes.

Figure 4. Process innovations in the Medtech sector by segment and time period

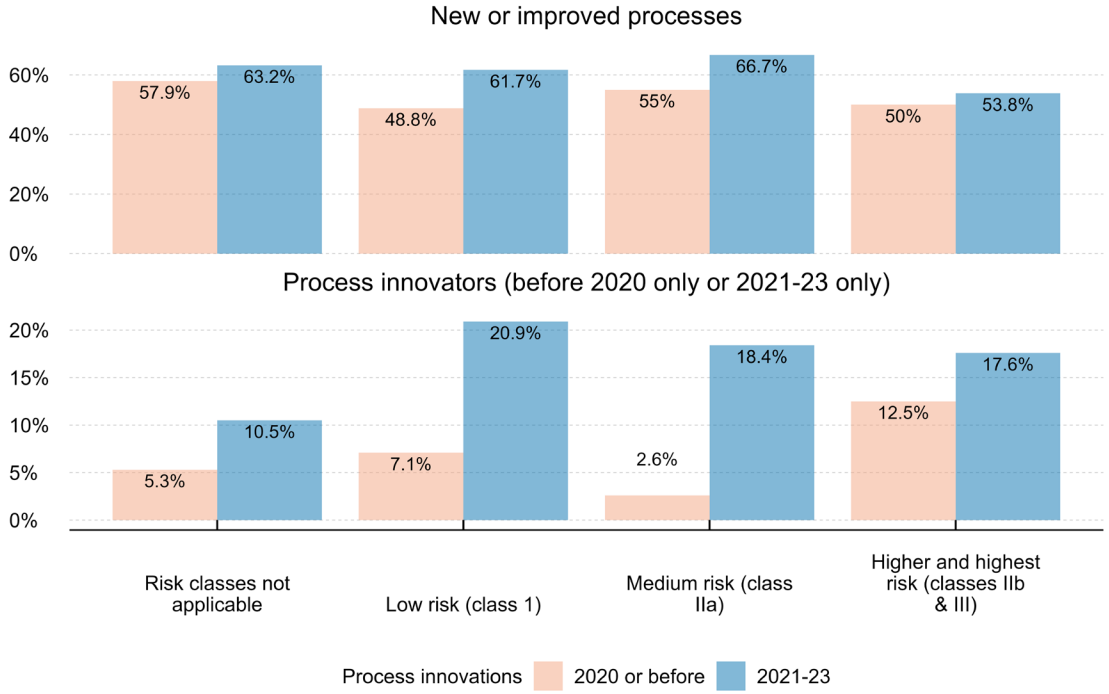
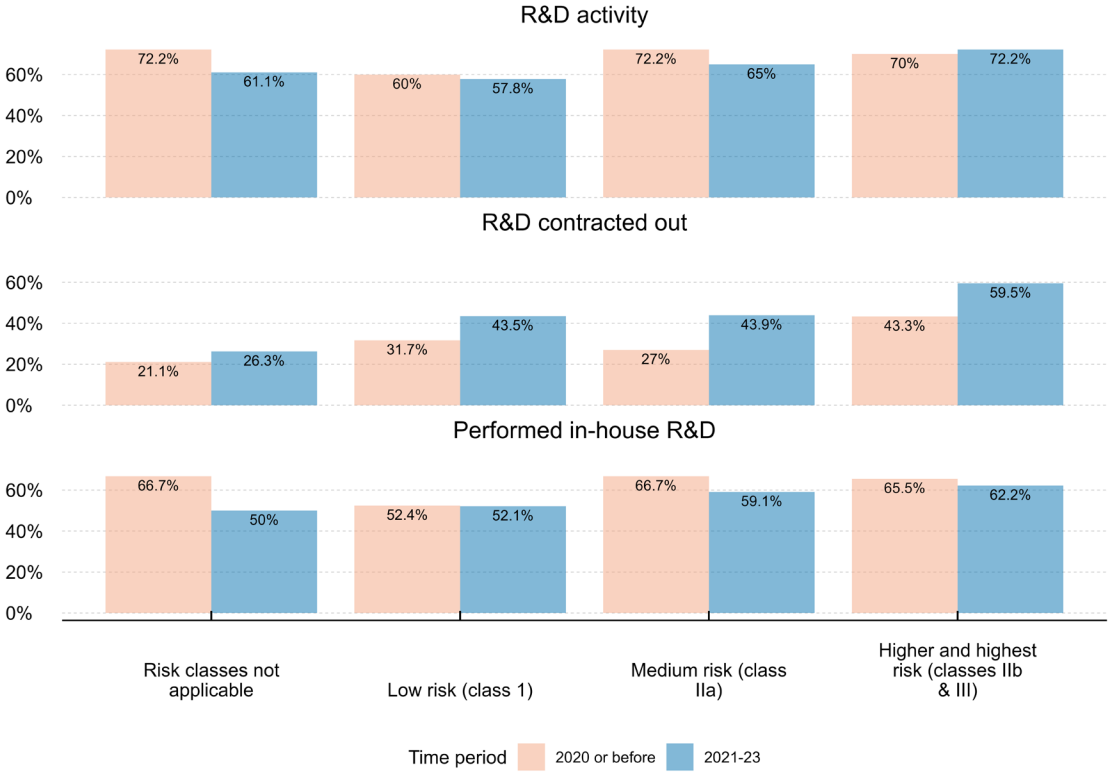


Figure 5. R&D activities in the Medtech sector by segment (in %)



Research and development activities

Figure 5, above, shows the share of companies with R&D activities (top panel), the share contracting out R&D (middle panel) and the share performing R&D in-house (bottom panel).

The situation differs between the segments: While we see overall a stagnation of the proportion of R&D active firms 2021-23 compared to 2020 and before, a decline is mainly visible among companies with no risk class. In the other risk classes the share of R&D active firms remained more or less the same or even increased. This development was predominantly driven by the decision to perform in-house R&D: in particular among companies with no risk class, a larger share stopped doing R&D internally. Across all risk classes more companies contracted out R&D activities in 2021-23 than before, the more so, the higher the risk class.

It appears that R&D has become less attractive for companies whose products are not subject to any risk classification. On the other hand, a greater proportion of companies in higher risk classifications, is conducting R&D, in particular, through external contracts. R&D activities in companies in the higher risk classifications are thus becoming more open.

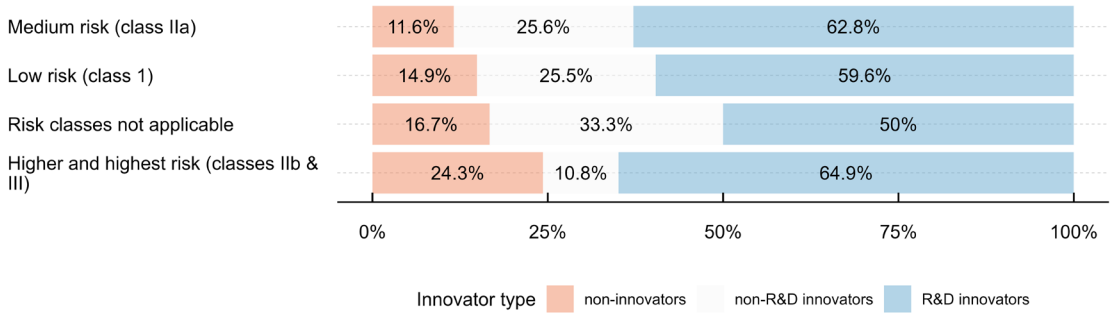
Innovator types

Figure 6 shows the shares of three different innovator types

- R&D innovators: companies introducing product or process innovation in 2021-23 and engaging in R&D (in-house or extramural),
- non-R&D innovators: companies introducing product or process innovation in 2021-23 but not engaging in R&D,
- non-innovators: companies not introducing product or process innovation in 2021-23

The higher the risk class, the more common are R&D innovators and the lower the risk class, the less common they are. Nearly two thirds of the companies in risk classes IIb-III are R&D innovators. Innovation without R&D is most common among companies without a risk classification – one third of these companies – and least common among the companies in the higher and highest risk classes. However, in this group the non-innovators are most frequent with one fourth of all companies in the higher and highest risk classes. There seems to be a fairly close link between conducting R&D and being able to innovate in the higher and highest risk classes – giving up R&D implies stopping to innovate. This connection is a lot less pronounced in the companies without a risk classification of their products as they find ways to innovate without R&D as well.

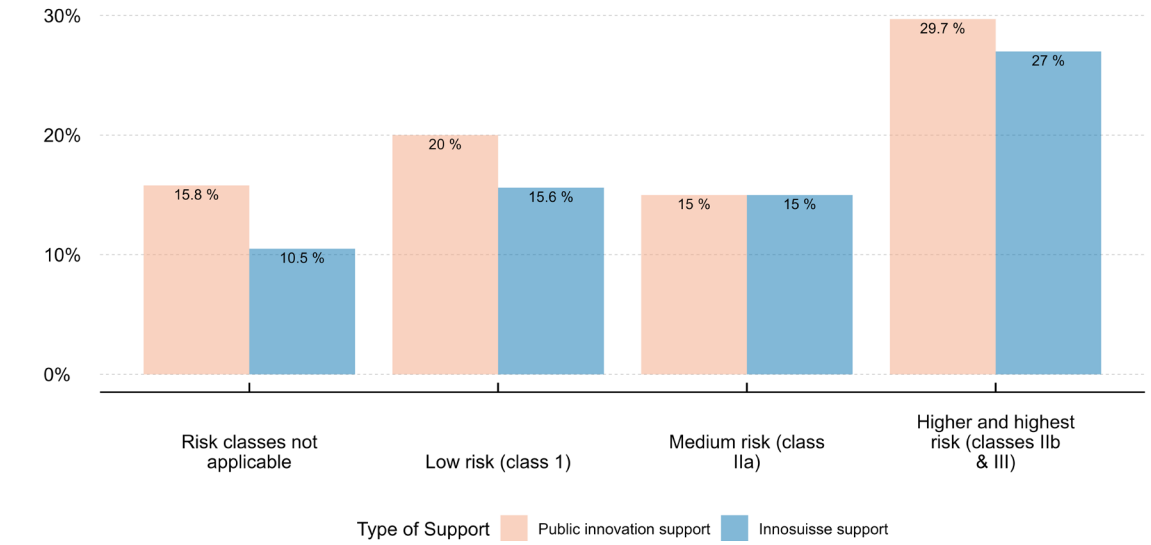
Figure 6. Innovator types in the Medtech sector by segment (in %)



Public innovation support

Approximately one out of five companies in the Medtech sector have received public support for their innovation activities (Figure 7). Most of them have benefitted from Innosuisse support. The share of companies that have obtained support is lowest for companies without a risk classification for their products, more or less equal for the lower and medium risk classes, and highest for the higher and highest risk classes (Figure 7). This is also a reflection of the higher commonness of R&D in the higher risk classes, as public innovation support, e.g. by Innosuisse, is connected to conducting R&D.

Figure 7. Use of public innovation support and Innosuisse support in the Medtech sector by segment (in %)



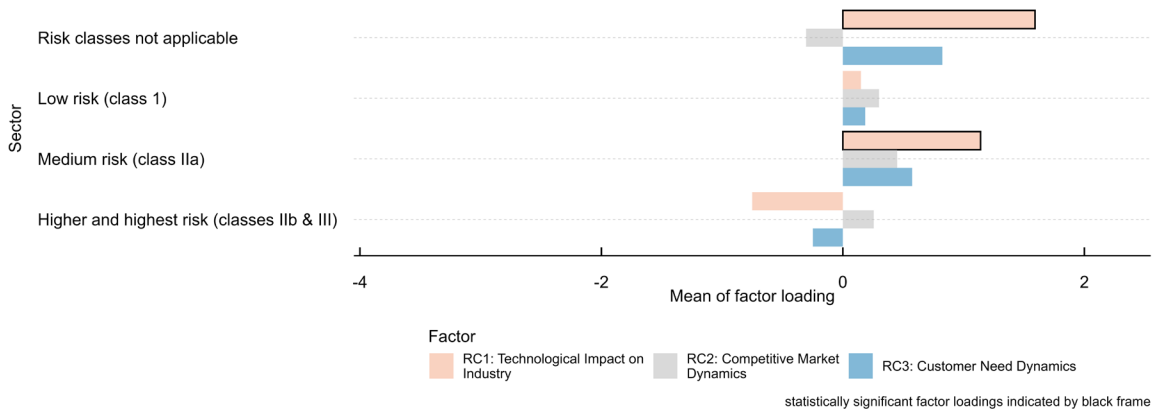
Note: The proportion of companies receiving Innosuisse support is included in the proportion receiving public innovation support.

3.2.2 Technology, competition and market dynamics

In order to identify the dynamics that companies see in their environment and whether this perception is linked to their innovation activities, the companies were asked five questions about each, the competitive environment and technological dynamics, and four on customer dynamics. These questions were then submitted to a principal component analysis (PCA) which resulted in three distinct components (see section 3.3 of the main report on further details):

- Factor RC1 primarily relates to the technological dynamics within the industry.
- Factor RC2 represents aspects related to price competition.
- Factor RC3 captures the shifting nature of customer demand and openness to new product ideas.

Figure 8. Mean factor loadings of customer, technology and market factors in the Medtech sector by segment



The factor loadings differentiated by sector illustrate to what extent the segments are affected by these customer-related, technological, and competition dynamics. We do not find significant differences between the risk classes for two of these three types of dynamics (Figure 8). Only for the opinions on the impact of technological dynamics on the industry (i.e. the assessments of speed and predictability of technological change, new technological opportunities, relevance of technological breakthroughs, and technological challenges and risks), the companies differ systematically by risk class. Companies for which risk classes are not applicable and companies in the medium risk class perceive higher technological dynamics, than companies in the higher and highest risk class. This would indicate that technological dynamics are not perceived as the main driver of companies' innovation activities.

3.2.3 Advances in digital technologies

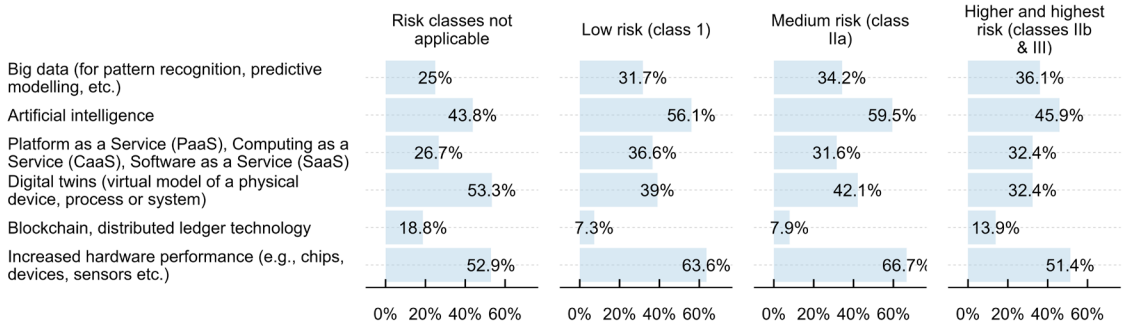
Further details on technological dynamics can be gleaned from the responses to the questions on the role of digital technologies for innovation.

The pattern varies by digital technology (Figure 9):

- The higher the risk classification the more often big data is perceived as important.
- The importance of artificial intelligence (AI) increases by risk class, but is lower again for companies in the higher and highest risk classes.
- New platform-based business models (PaaS & CaaS) seem to be of equal importance across the risk classes, except for companies without a risk classification of their products which least often attributed importance.
- In this latter group digital twins are perceived as important the most often whereas companies in the higher and highest risk classes give it rarely importance.
- Blockchains are of minor importance and hardware performance is of high importance across all four groups.

Hardware improvements seem to be the most relevant digitalisation enabler across all risk classes. AI matters more in the low and medium risk classes than in the other two groups, whereas digital twins matter more for companies without products with a risk classification. These diverse patterns do not suggest clear strengths and weaknesses. However, we can say that AI does not (yet) form the basis for fundamental changes among most of the companies in the higher and highest risk classes. This confirms the assessments of the Swiss Medtech Report (2024, p. 62) that only a minority of companies are using AI for innovation. Although there is undoubtedly growth potential here, the legal framework needs to be further developed.

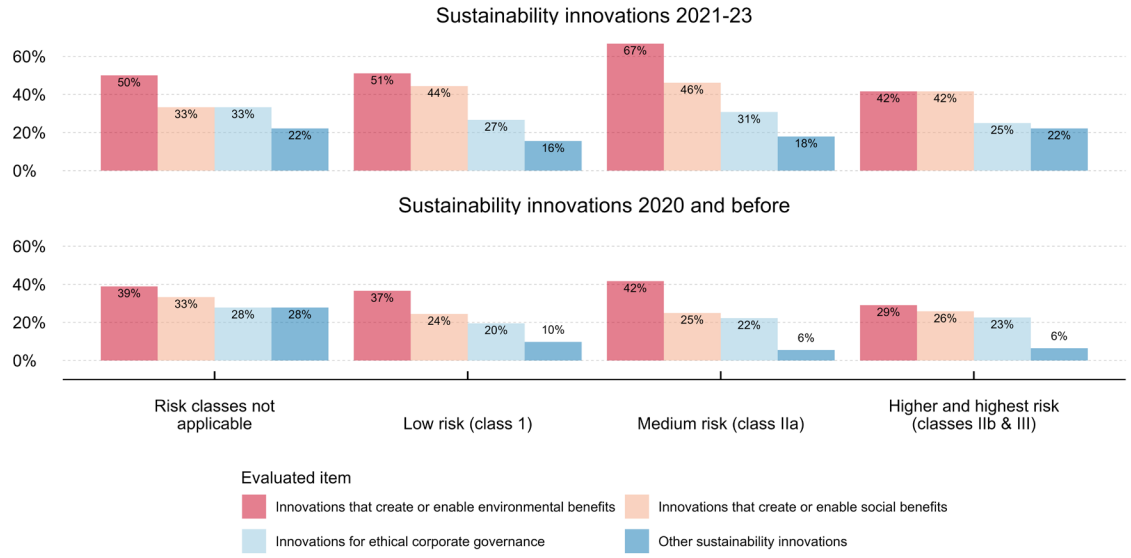
Figure 9: Share of companies perceiving advances in digital technologies as important in the Medtech sector by segment



3.2.4 Sustainability innovations

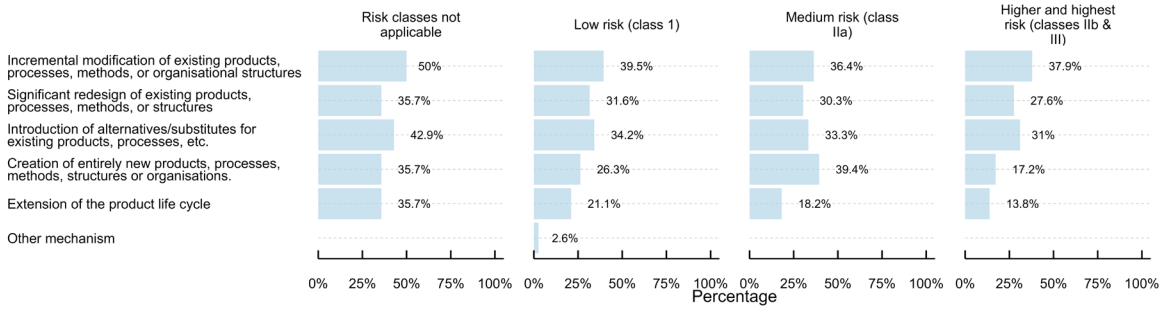
The analysis of recent developments in sustainable innovation between 2021/23 and the period before 2021 reveals limited variation across the segments in both the extent and type of innovation activities (Figure 10). The companies in the medium risk classes of products demonstrate the most significant overall progress, with notable increases across all categories, particularly environmental benefits, which rose by 25 percentage points. The other segments also show balanced improvements, reflecting a broad-based integration of sustainability considerations. Fewer companies in the higher and highest risk classes perceived environmental sustainability innovations the least often as important – this might be a reflection of the trade-offs between environmental benefits and contamination risks that has been described in the international literature (Hoveling et al., 2024; MacNeill et al., 2020; Sousa et al., 2021).

Figure 10. Sustainability innovations in the Medtech sector by segment in 2021/23 and 2020 and before (in %)



The use of all mechanisms of sustainability innovations is lower, the higher the risk class of the product with one exception: companies in the medium risk class most often answered that they created entirely new products, processes, methods, structures or organisations through their sustainability innovations (Figure 11).

Figure 11. Mechanisms of sustainability innovations with benefits for the environment, society, or governance in the Medtech sector by segment (in %)



3.2.5 Regulation and innovation

Two aspects of regulations can be differentiated by segments of the Medtech sector:

1) Types of regulations by importance,
2) Impacts of regulations on innovation activities

Ad 1) *Types of regulations.* Figure 12 shows which types of regulations are perceived as influential by the surveyed companies for their innovation activities. The patterns indeed differ between the risk classes.

For the companies in the higher and highest risk classes product-related regulations and process-related regulations are the most important ones, most likely reflecting the importance of the new European MDR/IVDR. More than 9 out of 10 companies perceived them as important. They are slightly less important in the other risk classes, above all for companies stating that their products do not fall under the risk classification. Companies in the higher and highest risk class are affected more by Intellectual Property regulations, most likely a reflection of their stronger focus on R&D-based innovation (see Figure 6 above).

Companies in the low and medium risk classes show very similar patterns with product- and process-related regulations also being the most important regulation types. Regulations on data-protection, environmental protection, employee safety, and markets are also perceived important by more than 70% of all firms in these risk classes. Above all the market-related regulations are less important for companies in the other risk classes.

The companies for which risk classes are not applicable point to regulations on environmental protection as the most important regulation type. All surveyed companies in this category perceive a significant impact on their innovation activities, whereas only half of the surveyed companies in the higher and highest risk class perceived environmental regulations as important for their innovation activities. The second most important regulation for these companies is data protection-related regulation.

Figure 12. Important regulations for innovation activities in the Medtech sector by segment (in %)

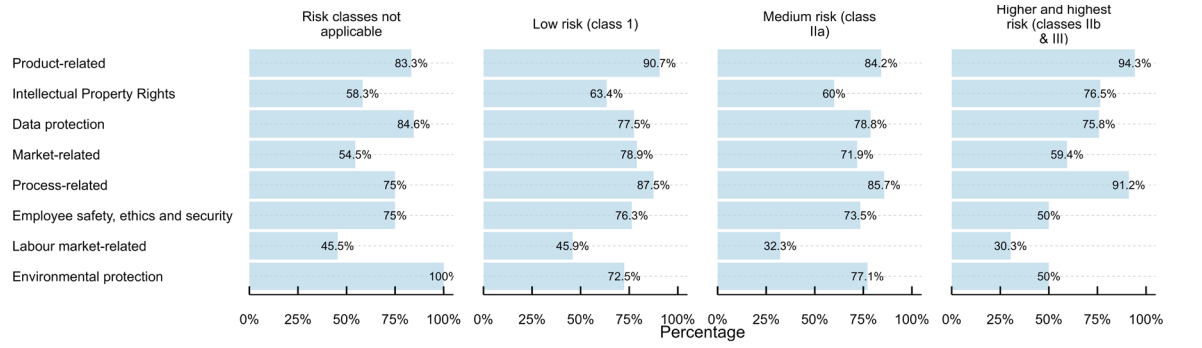
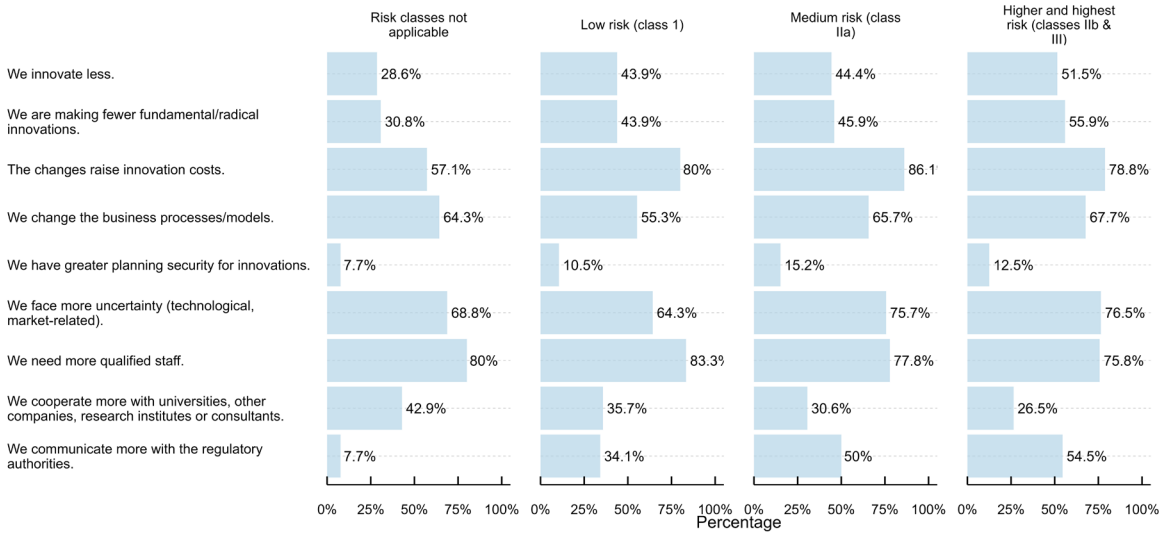


Figure 13 provides an overview of how companies across sectors have adjusted their innovation activities to regulatory changes between 2021 and 2023. Across all risk classes, companies feel higher innovation costs, a need for more qualified staff, and more technological and market-related uncertainty as the main implications of regulatory changes. Changes of the business processes or models were mentioned less often, but still by almost two thirds of the respondents. The main difference between the risk classes is that more adjustments are implemented the higher the risk class:

- In addition to the impacts that all companies feel, more than half of the companies in the higher and highest risk class pointed to fewer radical innovations, less innovation overall and more communication with regulatory authorities.

- Less than one out of twelve companies among those without risk classification perceived the need to communicate more with regulators. However, more cooperation with universities, other companies, research institutes or consultants was mentioned more often in this group.

Figure 13. Impact of regulation on the innovation activities in the years 2021-2023 in the Medtech sector by segment (in %)

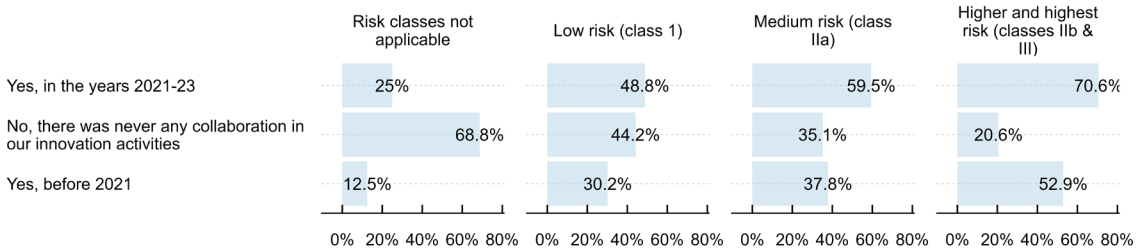


3.2.6 Innovation collaboration

In this section we report on the importance of collaboration and the main partners of the responding Medtech companies by segments.

Collaboration frequencies clearly differ by segment (Figure 14). While 70% of the companies for which the risk classes are not applicable have never collaborated in their innovation activities only 20% of the companies in the higher and highest risk classes have never collaborated. 70% of these companies in the higher and highest risk classes collaborated in 2021-23, up from 53% in 2020 and before.

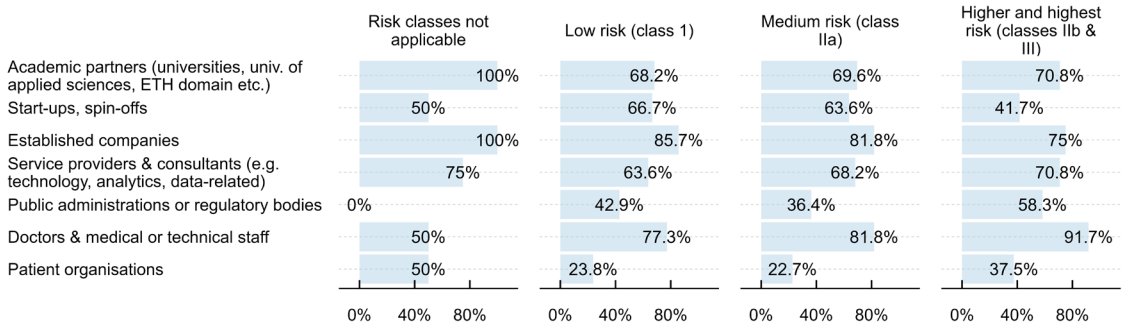
Figure 14: Innovation collaboration in the Medtech sector by segment (in %)



The importance of partners varies between the risk classes. Established companies are important for all companies, and even the more so, the *lower* the risk class, whereas doctors and medical or technical staff are more often important the *higher* the risk class (Figure 15). Academic partners are important for all companies without risk classification and for 70% of the other Medtech companies. Service & consulting providers are important for two thirds to three quarters of the Medtech companies. The higher importance of public administrations or

regulatory bodies in the higher and highest risk classes is in line with the increased communication in response to regulations reported above (Figure 13 above).

Figure 15: Important collaboration partners in the Medtech sector by segment (in %)



3.2.7 Summary

In Table 1 we tried to summarise the patterns from the survey per risk class in a SWOT structure. The baseline of the comparison is the total set of answers from Medtech companies in the dataset.

- *Risk class not applicable*: While there is a higher share of product innovators in this group, RD-based innovation is less common and fewer companies have introduced radical innovations. Regulatory changes generate above all uncertainty and a need for more staff – companies in this risk class are least affected among all the Medtech companies in this dataset by the specific Medtech problems created by tight regulatory frameworks. Technological change and environmental regulations matter most for this group, and both can create new business opportunities as well as constitute threats to existing businesses. However, it appears that companies themselves have a great deal of control over how they respond to these developments in their environment. The comparatively low importance of R&D, innovation cooperation and public innovation funding suggests that the primary approach in these companies relies least on the mechanisms of Swiss innovation policy.
- *Low risk class:* More companies with products in this risk category have open R&D activities, but overall fewer companies engage in R&D and conduct product innovation. While AI seems to be more relevant as a potential enabler of innovation, product-related and process-related regulations threaten innovation activities and generate higher innovation costs and a need for further staff. Companies in this risk class seem to react towards the regulatory challenges by engaging more in R&D and working more with external partners.
- *Medium risk class:* Looking at the SWOT pattern this group seems to cope best with the existing challenges and maintain a broad innovation focus. In some regards it is similar to the low risk class group, but more often engaging in R&D and generating (radical) sustainability innovations. AI is also more of an enabler, whereas product-related and process-related regulations threaten innovation activities and generate uncertainty, higher innovation costs and a need for further staff.
- *Higher and highest risk classes:* Stronger focus on R&D than in the other three groups and larger share of companies which are supported by innovation policy. Higher share of companies involved in innovation collaboration. However, innovation outputs with regard to products, processes, and sustainability innovations are less common. Product-related and process-related regulations have several negative impacts, above all higher innovation costs, fewer (radical) innovations, higher uncertainty and need for more staff. This group of firms is the one that is most focused on

R&D, internally as well as in collaboration with a broad set of external partners. However, it is also the group most affected by the specific Medtech problems, above all the complex market environment of the health sector and the tight regulatory frameworks which have reduced companies' abilities to innovate successfully.

Table 1. Strengths, weaknesses, opportunities & threats by risk class

Risk class not applicable	
Strengths More product (goods and service) innovators	**Weaknesses** Fewer radical innovators (above all services) Fewer companies with R&D activities Less innovation collaboration
Opportunities Technological change Environmental regulation	**Threats** Technological change Environmental regulation Higher staff need because of regulation Higher uncertainty because of regulation
Low risk class	
Strengths More companies with open R&D activities	**Weaknesses** Fewer product innovators Fewer companies with R&D activities
Opportunities AI as enabler	**Threats** More companies affected by product-related and process-related regulations Higher innovation costs because of regulation Higher staff need because of regulation
Medium risk class	
Strengths More companies with open R&D activities More (radical) sustainability innovators	**Weaknesses**
Opportunities AI as enabler Technological change	**Threats** Technological change More companies affected by product-related and process-related regulations Higher innovation costs because of regulation Higher uncertainty because of regulation Higher staff need because of regulation
Higher and highest risk classes	
Strengths More companies with R&D activities More companies with open R&D activities More R&D innovators Larger share of publicly supported companies More innovation collaboration	**Weaknesses** Fewer product innovators Fewer process innovators More non-innovators Fewer (radical) sustainability innovators
Opportunities	**Threats** More companies affected by product-related and process-related regulations Higher innovation costs because of regulation Fewer (radical) innovations because of regulation Higher uncertainty because of regulation Higher staff need because of regulation

Note: All assessments are made relative to the Medtech sector total.

4 Sector-specific results of the Delphi interviews

To further analyse the innovation-related problems in each sector and develop policy recommendations which could remove obstacles and support companies' innovation activities, we conducted two rounds of Delphi interviews with the management of companies from the sector. Round 1 consisted of individual interviews and round 2 of a group discussion.

The statements presented in this section are based on the contributions made during these interviews. They reflect the individual perceptions and experiences of the participants. The statements were not subjected to any further in-depth review or validation as part of this study. The results are sector-specific and should not be generalised to other sectors or to the Innosuisse innovation promotion system as a whole.

4.1 Data basis and approach

Round 1: The data basis of round 1 are 10 interviews, six with small firms with up to 49 employees, 1 with a mid-sized company with 50-249 employees, and three with larger companies with more than 250 employees. The bilateral interviews with a company representative were conducted virtually, commonly by two researchers. The interviews used a semistructured interview guide (see Appendix 12 of the main report).

Round 2: In the group discussion in round 2 seven companies, three further participants and the research team participated. Participants received before the discussion a two-page factsheet summarizing the main sector results of the survey and the Delphi round 1 interviews. During the workshop, they could select from the topics of round 1 and were then asked to discuss predominantly policy measures that would help to address the identified issues. The Medtech discussions went beyond mere policy suggestions and participants also extended and deepened the analyses of round 1.

The summaries of both rounds follow below. The key points of both rounds were summarised in an overview file and a transcript, which were then further reduced by the research team manually and with the aid of AI tools (Perplexity, Chatgpt) and evaluated for patterns (similarities, differences).

4.2 Results of Delphi rounds 1 and 2

Delphi round 1

Across the collected statements from Swiss MedTech firms and related actors, several overarching patterns emerge regarding the focus of innovation, drivers and barriers, and the roles of digitalization, regulation, sustainability, and collaboration.

1. Focus of innovation activities. Innovation efforts in the Swiss MedTech sector concentrate strongly on digital transformation, incremental product improvements, and, in some niche areas, radical technological developments driven primarily by start-ups rather than large firms. Established companies increasingly rely on external expertise, such as universities, suppliers, and specialists in adjacent fields, to compensate for internal constraints. In many firms, innovation is application-oriented, targeting process optimization (e.g., ERP harmonization, AI-assisted inspection), clinical improvement, or customized patient solutions (e.g., robotics, prosthetics, 3D scanning).

Medtech companies acknowledged that Innosuisse plays an important and positive role in technology transfer. However, criticism was also expressed by the interview partners regarding Innosuisse's support: Too little support in finding partners, too strong a focus on Swiss research partners, too university- and cooperation-oriented, no direct funding for companies, a strong focus on academic start-ups and little understanding of SME's needs.

2. Influences on innovation. Innovation in Medtech is shaped by a combination of internal organizational factors (innovation culture, talent availability, motivation, strategic orientation)

and external influences (market competition, regulatory shifts, international competitive pressure, access to data, and technological trends). Many respondents emphasize that innovation culture and talent retention are more decisive than direct financial support. At the same time, Swiss SMEs face substantial funding gaps, especially in bridging long development cycles and bringing products to market. International competition – particularly from the U.S. and China – is increasingly relevant, with Chinese firms perceived as fast followers and with U.S. markets offering far more attractive commercialization conditions.

3. Role and effects of digitalization. Digitalization emerges as one of the most important innovation domains. Across firms, it is linked to:

- Data-driven product development and diagnostics (AI, tele-health, visual inspection),
- Process optimization via cloud-based ERP, CAD systems, automation,
- New forms of customization (3D scanning for prosthetics),
- New digital business models (pay-per-use service models).

However, significant challenges exist. In Medtech, AI validation is particularly complex, as model errors can directly endanger patients. Fragmented European data protection rules, lack of patient data access in Switzerland, and federalist fragmentation (e.g., cantonal e-health differences) severely limit digital innovation. The unsatisfactory access to patient data, even anonymised data for analysis, was repeatedly cited as an obstacle to innovation. Digital innovations that use AI applications are virtually impossible without such data. Companies highlight the need for centralized, standardized, and anonymized health-data platforms, as well as sector-wide agreements on data use. Cooperation with research institutions, regulatory bodies (the federal government and cantons) and other stakeholders in the healthcare sector is seen as a way of overcoming these difficulties, both now and in the future. SMEs also struggle to identify which digital solutions (applications, processes, products, etc.) genuinely add value.

4. Regulatory influences on innovation. Regulation is the dominant barrier discussed across almost all firms. Key issues include:

a) Medical Device Regulation (MDR) in the EU is described as overly heavy, costly, bureaucratic, and slow. It doubles compliance costs in some cases and shifts employees away from laboratory work toward administrative tasks. It hinders incremental innovation because even minor product adjustments require full certification procedures – the bureaucratic product certification requirements that do not differentiate sufficiently according to the extent of a change and drive up innovation costs. It limits the ability to iterate rapidly and launch early versions for feedback. The rigid regulations do not sufficiently permit experimentation, and do not consider cost aspects (e.g. with regard to reuse, recycling, packaging, etc.).

b) Swiss regulatory challenges. Approval processes for clinical trials lack transparency, predictability, and timely communication. The lack of pre-submission consultation with Swissmedic hinders study design. Overall, Switzerland's dependence on EU regulatory frameworks makes the system less agile.

c) Calls for regulatory reform. Stakeholders consistently propose:

- Regulatory sandboxes for experimental testing (with reduced compliance burden),
- Small, fast-track clinical trials for early-stage innovations,
- Acceptance of FDA approvals in Switzerland to enable faster market entry,
- Standardized cooperation contracts for university–industry projects,
- Harmonization of privacy laws and clearer digital-health regulations.

Regulation is viewed as lagging 10-15 years behind technological development, demotivating innovators and often making conventional solutions more attractive than novel ones.

5. Sustainability innovation. Sustainability is perceived in nuanced ways: For some firms, sustainability is not yet a core innovation driver but is increasingly important for talent attraction, corporate reputation, and future market expectations. In several cases, sustainability ambitions conflict directly with regulatory requirements, particularly bans on reusing or refurbishing components (e.g., in prosthetics), mandatory single-use plastics, or individualized packaging under MDR. Companies highlight a trade-off when it comes to achieving the triple bottom line of social, economic and environmental sustainability: while restrictions in current regulations (e.g. on reuse, reprocessing, recycling and packaging) are in place to prevent contamination and increase patient safety, they also generate higher environmental costs. This conflict must be overcome through appropriate procurement rules for hospitals and healthcare providers, for example, and supportive product requirements. Some firms pursue circular-economy approaches, recycled materials, and “cradle-to-cradle” strategies, but systemic barriers (costs, rules, lack of reuse markets) limit implementation. Emerging signals (e.g. large tenders and hospital procurement) suggest sustainability will become more important in the near future.

Overall, sustainability is more of a latent pressure than an active innovation incentive, except in firms whose identity or workforce motivation is tightly linked to sustainable values.

6. Collaboration and its challenges. Collaboration is universally acknowledged as essential for innovation, but access and effectiveness vary substantially:

a) Key collaboration partners are universities (ETH domain, UAS, Balgrist), suppliers (critical for development speed and technical expertise), start-ups (source of radical innovation), or international experts (e.g. especially important in specialized fields like prosthetics), other companies via associations or informal networks.

b. Barriers to effective cooperation are: complex, slow, and costly university collaboration processes, discontinuity when academic chairs or research groups disappear, limited inclusion of international expertise in publicly funded programs, lack of institutional platforms for partner search and matchmaking, high entry costs demanded by large industry partners for collaboration, talent shortages limiting absorptive capacity, closed innovation ecosystems (e.g., Innosuisse funding predominantly benefiting universities), and fragmented regulations obstructing cross-border innovation cooperation

c. Needed improvements. Stakeholders recommended: 1) moderated round tables, with science potentially playing an important role as a “neutral” partner, 2) simplified partnership search and formation for SMEs, 3) standardized collaboration contracts, 4) fundable innovation partnerships with non-academic innovators, 5) financial incentives to reduce risks of collaboration, 6) lower-threshold innovation support for SMEs.

Collaboration is thus simultaneously a key innovation driver and an area with structural weaknesses, especially for smaller firms.

Overall Assessment. The collected insights portray a dynamic Swiss Medtech ecosystem with strong competencies, high motivation, and significant digital and scientific potential. However, the innovation capacity is increasingly constrained by regulatory overload, funding gaps for market translation, fragmented digital infrastructures, and collaboration inefficiencies. While sustainability and digitalization are emerging as essential themes, their impact is moderated by systemic constraints. Strategic reforms – particularly in regulation, clinical trial procedures, digital-health governance, and SME-oriented innovation support – are repeatedly cited as necessary to maintain Switzerland’s competitive position and to foster future-oriented Medtech innovation.

Policy suggestions by the Delphi participants

In the bilateral discussions with Medtech companies emerged several suggestions for policy measures of varying scope and precision:

1. The creation of regulatory sandboxes (small-scale, time-limited exemptions and controlled clinical testing environments) and experiments in which product development and testing are permitted under conditions that are functional for companies. The scope of the sandboxes must be broad enough to allow experiments that could lead to fundamental reforms, e.g. of clinical trial processes or the creation of secondary markets for medical devices.
2. Establish time-bound pre-submission consultations with Swissmedic (formalize "pre-check" meetings so sponsors receive protocol feedback before full submission) to reduce wasted effort and accelerate iteration.
3. Financing innovation projects, possibly without scientific or cooperative involvement, but with foreign partners if necessary. This should include financing solutions for later stages, clinical phases, and company expansion, in order to reduce out-migration.
4. Create SME-focused bridge funds with multi-year commitments (≥5 years) targeted at the "valley of death" (scaling clinical validation, regulatory certification). Instruments should include milestone financing and matchmaking to clinical sites. (Matches calls for predictable multi-year funding.)
5. Develop a secure, governance-cleared Swiss health-data access model for anonymized research datasets (national or federated biobank/access portal) with clear opt-out/consent pathways and technical safeguards – enabling AI validation while protecting privacy. This should be interoperable with EU frameworks.
6. Granting Innosuisse a more proactive role in initiating and moderating discourse, brokering partnerships, selecting and funding promising innovation projects, monitoring funded projects, and evaluating results. Project selection and monitoring need to be improved.
7. Set up national SME partner-matching platforms and standardized IP/collaboration contract templates to reduce negotiation costs and increase university-SME cooperation.
8. Commission a regulatory review for circular-economy pathways in Medtech to identify where safe reuse/refurbishment can be enabled (e.g., secondary markets for assistive devices) and where single-use rules are legitimately required. Pilot reuse programmes under sandbox conditions where safe.
9. Strengthen talent development, skills and education (digital competencies, vocational training) and international (STEM) talent attraction.

Delphi round 2

A summary of the first-round results for the sector was shared with the participants with an invitation to the second-round (group) discussion. When asked which results should be prioritised, the Medtech sector company representatives selected and discussed intensively four topics in the second Delphi round: 1) Regulation, 2) Collaboration, 3) Financing of start-ups and innovation, and 4) Data.

Ad 1.) Make regulation more innovation friendly. While regulatory frameworks are essential for protecting patients and understanding their purpose, they differ significantly across jurisdictions such as Europe, Switzerland, and the United States, which increases costs for companies operating internationally. Moreover, regulatory requirements often lag behind current research and technological applications, creating legal uncertainty for innovators.

Switzerland is perceived as an unattractive location for clinical testing due to long approval processes, and pursuing approvals abroad – particularly in China or the United States – is financially difficult for many firms.

Experiences with U.S. regulations and their implementation by the FDA vary widely, reinforcing uncertainty. Companies also do not always fully understand the intent of specific regulations, and interpretations differ between European Notified Bodies.

As a result, firms express a strong need for support in implementing regulatory requirements, including clear explanations and feedback on proposed solutions. To address these issues, several measures are proposed: aligning Swiss regulations with the EU framework but reducing their scope where they are not applicable to Switzerland; accepting FDA-approved products through a fast-track procedure; adopting a risk-based approach with reduced requirements for lower-risk device classes; and increasing trust in companies, which have inherent incentives to ensure patient safety. Regulatory “sandboxes” would allow firms to test new devices without completing the full approval process and to engage in early discussions with regulators. International examples of fast-track clinical testing, such as in Australia, New Zealand and Canada, offer useful models.

Ad 2) Strengthening collaboration and partnership ecosystems. A substantial gap exists between academia and industry, with communication challenges hindering effective cooperation: more low-threshold, frequent exchanges are needed to align project goals. Negotiating collaboration terms – particularly concerning IP ownership and publication rights – remains difficult, and SMEs often struggle to find suitable partners, resorting to generic online searches or cold calls. Universities of Applied Sciences (UAS) tend to be more accessible and pragmatic partners.

Proposed measures include providing standard IP templates by funders, such as Innosuisse, ensuring publication rights remain with universities while IP ownership stays with companies. A platform for regular exchange between science and industry would help bridge cultural and communication gaps, and a dedicated Medtech roundtable involving industry, academia, and regulators would institutionalize this dialogue. Additional incentives and information channels are needed to support collaboration across disciplinary silos.

Ad 3) Strengthen start-up and innovation financing across all stages. Individual participants report that Innosuisse guidelines and requirements are not fully transparent to them, while current funding criteria seem to exclude foreign-owned companies even when their R&D activities take place in Switzerland. A persistent funding gap affects SMEs, and financing clinical tests and regulatory approvals is particularly challenging due to the risk aversion of Swiss and European investors. Discussions on mobilizing pension funds for innovation have continued for more than a decade without meaningful progress.

Proposed measures include simplifying the Innosuisse application process through shorter submissions, faster reviews, and more transparent decisions; introducing a two-step application process; allowing applicants to present projects orally after submission; and revising eligibility criteria to focus on the location of R&D rather than ownership. Innosuisse should also support R&D and innovation collaboration among Swiss companies. Additional policy tools could include tax incentives for startup investment, deploying Swiss National Bank capital to support scale-up financing, and issuing funding calls for cross-disciplinary areas such as digital health, which would stimulate broader collaboration and attract complementary private investment – an area where Switzerland currently lacks targeted funding.

Ad 4) Greater openness and sharing of data. Current regulations governing patient-data confidentiality impose excessively high compliance burdens, hindering research and innovation. A fully implemented Electronic Patient Dossier (ePD) could significantly accelerate innovation, and with an appropriate framework Switzerland could turn data governance into a competitive advantage. Anonymized data is generally sufficient for research purposes, and standardization is essential to link diverse data elements associated with individual patients.

Measures to increase data openness include expanding opportunities for patients to voluntarily donate their data for research and drawing on leading international examples such as Sweden's centralized health data systems or the UK Biobank.

Finally, talent development, skills, and education must be reinforced. Switzerland benefits from strong local talent but faces challenges attracting specialists from the United States, where innovation cycles are faster and opportunities abundant. Introducing special work permits for individuals with exceptional or highly unique skills could help attract top international talent and ensure continued competitiveness.

We refrain from making sector-specific policy recommendations, as the policy recommendations made in the main report (section 5) apply to all sectors with possible sector-specific adjustments. We also refrain from adding a conclusion section, as the executive summary contains a detailed summary of the literature review, survey findings, and Delphi interview results.

References

Auer, A., & Jarmai, K. (2018). Implementing Responsible Research and Innovation Practices in SMEs: Insights into Drivers and Barriers from the Austrian Medical Device Sector. *Sustainability*, *10*(1), Article 1. https://doi.org/10.3390/su10010017

Barberá-Tomás, D., & Consoli, D. (2012). Whatever works: Uncertainty and technological hybrids in medical innovation. *Technological Forecasting and Social Change*, *79*(5), 932–948. https://doi.org/10.1016/j.techfore.2011.12.009

Barbero, S., Pereno, A., & Tamborrini, P. (2017). Systemic innovation in sustainable design of medical devices. *The Design Journal*, *20*(sup1), S2486–S2497. https://doi.org/10.1080/14606925.2017.1352763

Barjak, F., Foray, D., & Wörter, M. (2023). *Mastering multiple complexities – a rising challenge for Swiss innovation models*. State Secretariat for Education, Research and Innovation SERI. https://www.sbfi.admin.ch/en/publication?id=xF0yYg1ufwCQ

Barth, T., Göldner, M., & Spitzenberger, F. (2021). Einfluss von regulatorischen Anforderungen auf Innovationen in der Medizintechnik am Beispiel der europäischen Medical Device Regulation („MDR“) und des nationalen Digitale-Versorgung-Gesetzes („DVG“). In M. Bodemann, W. Fellner, & V. Just (Eds), *Zukunftsfähigkeit durch Innovation, Digitalisierung und Technologien: Geschäftsmodelle und Unternehmenspraxis im Wandel* (pp. 223–252). Springer. https://doi.org/10.1007/978-3-662-62148-6_10

Blume, S. S. (1995). Cochlear implantation: Establishing a clinical feasibility, 1957–1982. In N. Rosenberg, A. C. Gelijns, & H. Dawkins (Eds), *Sources of Medical Technology: Universities and Industry* (pp. 97–124). National Academies Press. https://doi.org/10.17226/4819

Ciani, O., Armeni, P., Boscolo, P. R., Cavazza, M., Jommi, C., & Tarricone, R. (2016). *De innovatione*: The concept of innovation for medical technologies and its implications for healthcare policy-making. *Health Policy and Technology*, *5*(1), 47–64. https://doi.org/10.1016/j.hlpt.2015.10.005

Daniore, P., Zavattaro, F., & Gille, F. (2024). *Public Trust in a Swiss Health Data Space*. Universität Zürich. https://health.dsi.uzh.ch/app/uploads/2024/03/Daniore-Zavattaro-Gille-2024-Public-Trust-in-a-Swiss-Health-Data-Space.pdf

De Pietro, C., & Francetic, I. (2018). E-health in Switzerland: The laborious adoption of the federal law on electronic health records (EHR) and health information exchange (HIE) networks. *Health Policy*, *122*(2), 69–74. https://doi.org/10.1016/j.healthpol.2017.11.005

European Commission. Directorate-General for Research and Innovation, Gilbert, S., Cavicchi, B., Vuorinen, H., & Florindi, F. (2025). *EU R&I policy as an enabler of MedTech innovation*. Publications Office of the European Union. https://data.europa.eu/doi/10.2777/4917399

Guerra-Bretaña, R. M., & Flórez-Rendón, A. L. (2018). Impact of regulations on innovation in the field of medical devices. *Research on Biomedical Engineering*, *34*, 356–367. https://doi.org/10.1590/2446-4740.180054

Hennein, R., Goddard, E., & Sherman, J. D. (2022). Stakeholder perspectives on scaling up medical device reprocessing: A qualitative study. *PLOS ONE*, *17*(12), e0279808. https://doi.org/10.1371/journal.pone.0279808

Hoveling, T., Svindland Nijdam, A., Monincx, M., Faludi, J., & Bakker, C. (2024). Circular economy for medical devices: Barriers, opportunities and best practices from a design perspective. *Resources, Conservation and Recycling*, *208*, 107719. https://doi.org/10.1016/j.resconrec.2024.107719

Kearney, B., & McDermott, O. (2023). Challenges faced by manufacturers with clinical evaluation under the new European Medical Device Regulations. *Cogent Engineering*, *10*(2), 2261236. https://doi.org/10.1080/23311916.2023.2261236

Knape, T., Hufnagl, P., & Rasche, C. (2020). Innovationsmanagement unter VUKA-Bedingungen: Gesundheit im Fokus von Digitalisierung, Datenanalytik, Diskontinuität und Disruption. In M. A. Pfannstiel, K. Kassel, & C. Rasche (Eds), *Innovationen und Innovationsmanagement im Gesundheitswesen: Technologien, Produkte und Dienstleistungen voranbringen* (pp. 1–24). Springer Fachmedien. https://doi.org/10.1007/978-3-658-28643-9_1

Krieger, B., & Zipperer, V. (2022). Does green public procurement trigger environmental innovations? *Research Policy*, *51*(6), 104516. https://doi.org/10.1016/j.respol.2022.104516

Kruse, C. S., Kristof, C., Jones, B., Mitchell, E., & Martinez, A. (2016). Barriers to Electronic Health Record Adoption: A Systematic Literature Review. *Journal of Medical Systems*, *40*(12), 252. https://doi.org/10.1007/s10916-016-0628-9

Ladd, M. E. (2023). The Medical Device Regulation and its impact on device development and research in Germany. *Zeitschrift Für Medizinische Physik*, *33*(4), 459–461. https://doi.org/10.1016/j.zemedi.2023.09.002

MacNeill, A. J., Hopf, H., Khanuja, A., Alizamir, S., Bilec, M., Eckelman, M. J., Hernandez, L., McGain, F., Simonsen, K., Thiel, C., Young, S., Lagasse, R., & Sherman, J. D. (2020). Transforming The Medical Device Industry: Road Map To A Circular Economy. *Health Affairs*, *39*(12), 2088–2097. https://doi.org/10.1377/hlthaff.2020.01118

Maresova, P., Hajek, L., Krejcar, O., Storek, M., & Kuca, K. (2020). New Regulations on Medical Devices in Europe: Are They an Opportunity for Growth? *Administrative Sciences (2076-3387)*, *10*(1), 16. https://doi.org/10.3390/admsci10010016

MedTech Europe. (2020). *Innovation in Medical Technologies. Reflection Paper.* https://www.medtecheurope.org/resource-library/innovation-in-medical-technologies-reflection-paper/

Metcalfe, J. S., James, A., & Mina, A. (2005). Emergent innovation systems and the delivery of clinical services: The case of intra-ocular lenses. *Research Policy*, *34*(9), 1283–1304. https://doi.org/10.1016/j.respol.2005.01.015

Mikhailova, O. (2022). Chapter 12: Interactions in innovation processes of medical devices: systemic and network perspectives. In Beniamino Callegari, Bisrat A. Misganaw, & Stefania Sardo (Eds), *Rethinking the Social in Innovation and Entrepreneurship* (pp.

234–256). Edward Elgar Publishing Ltd. https://www.elgaronline.com/edcollchap-oa/book/9781839108174/book-part-9781839108174-22.xml

Morlacchi, P., & Nelson, R. R. (2012). The evolution of the left ventricular assist device as a treatment for heart failure. In D. Consoli, A. Mina, R. R. Nelson, & R. Ramlogan (Eds), *Medical Innovation: Science, technology and practice* (1st edn, pp. 48–68). Routledge. https://www.routledge.com/Medical-Innovation-Science-technology-and-practice/Consoli-Mina-Nelson-Ramlogan/p/book/9780367668686

Nusser, M., & Lindner, R. (2010). Gestaltungsoptionen für eine zukunftsorientierte Innovationspolitik in der Medizintechnik. *Zeitschrift Für Evidenz, Fortbildung Und Qualität Im Gesundheitswesen*, *104*(10), 709–714. https://doi.org/10.1016/j.zefq.2010.08.004

Oruezabala, G., & Rico, J.-C. (2012). The impact of sustainable public procurement on supplier management—The case of French public hospitals. *Industrial Marketing Management*, *41*(4), 573–580. https://doi.org/10.1016/j.indmarman.2012.04.004

Slawomirski, L., Lindner, L., Bienassis, K. de, Haywood, P., Hashiguchi, T. C. O., Steentjes, M., & Oderkirk, J. (2023). *Progress on implementing and using electronic health record systems: Developments in OECD countries as of 2021*. OECD Publishing. https://dx.doi.org/10.1787/4f4ce846-en

Sousa, A. C., Veiga, A., Maurício, A. C., Lopes, M. A., Santos, J. D., & Neto, B. (2021). Assessment of the environmental impacts of medical devices: A review. *Environment, Development and Sustainability*, *23*(7), 9641–9666. https://doi.org/10.1007/s10668-020-01086-1

Stähle, L. (2020). *Enabling digital service innovation in medical technology firms: An organizational capability perspective*. Universität St. Gallen.

Stern, A. D. (2017). Innovation under regulatory uncertainty: Evidence from medical technology. *Journal of Public Economics*, *145*, 181–200. https://doi.org/10.1016/j.jpubeco.2016.11.010

Swissmedic (2025). *Swissmedic is improving the framework conditions for clinical studies in Switzerland.* https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/publikationen/visible/swissmedic-visible-aug-2025.spa.v11.app/en/clinical-studies.html

Swiss Medtech, Helbling. (2024). *Die Schweizer Medizintechnikindustrie. Branchenstudie 2024.* https://www.swiss-medtech.ch/sites/default/files/2024-09/SMTI_2024_Bericht_240904_DE.pdf

Swiss Medtech, Helbling. (2022). *Schweizer Medizintechnikindustrie. Branchenstudie 2022.* https://www.swiss-medtech.ch/sites/default/files/2022-09/22_2769_SMTI_2022_Deutsch.pdf

Tsai, C. H., Eghdam, A., Davoody, N., Wright, G., Flowerday, S., Koch, S., Tsai, C. H., Eghdam, A., Davoody, N., Wright, G., Flowerday, S., & Koch, S. (2020). Effects of Electronic Health Record Implementation and Barriers to Adoption and Use: A Scoping Review and Qualitative Analysis of the Content. *Life*, *10*(12). https://doi.org/10.3390/life10120327