Responsible Digital Health Innovation Roadmap

For policymakers and decision-makers

ETH zürich Health Ethics & Policy Lab Swiss National Science Foundation 77 NRP Digital Transformation National Research Programme

Underlying research

The recommendations in this Roadmap are based on research conducted by the Health Ethics & Policy Lab, ETH Zurich. Over 70 senior stakeholders were engaged in our research activities, including regulatory bodies, large pharmaceutical and technology companies, start-ups, and patient representatives.[1-2] Their insights were instrumental in identifying challenges and exploring potential solutions. This research approach helps to ensure that the various perspectives and needs of actors in the Swiss healthcare system are addressed in this Roadmap. This work was possible thanks to the support of the Swiss National Science Foundation (SNSF) (NRP77 grant N. 407740_187356). For details on the methodologies and findings that shaped this Roadmap, please refer to key publications.[1-6]

The Health Ethics & Policy Lab

The Health Ethics & Policy Lab is an interdisciplinary research team based at ETH Zurich. We investigate ethical issues, regulatory challenges, and policy solutions in precision medicine and digital health. Our aim is to promote responsible innovation and foster an equitable and sustainable healthcare system.

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Responsible digital health has been defined as:

> "any intentional systematic effort designed to increase the likelihood of a digital health technology developed through ethical decision making, being socially responsible and aligned with the values and well-being of those impacted by it."[7]

Executive summary

This Roadmap seeks to promote responsible digital health innovation in Switzerland by presenting four governance principles and eight concrete actions for policymakers and decision-makers in the digital health ecosystem. Governance principles are action guides indicating what should be done to achieve desirable governance goals.

The rapid pace of innovation in digital health, particularly with artificial intelligence (AI), presents complex challenges for our current governance models. These technologies raise multifaceted considerations regarding data privacy, cybersecurity, ethical implications, and economic impact. Moreover, predicting and managing their long-term effects is also increasingly difficult.

To govern technological innovation and address the challenges of rapid developments and implementations, policymakers and decision-makers across the healthcare ecosystem should adopt innovative governance principles. These are summarised as follows:

Agile Regulation

Policymakers and decision-makers can enable agile regulation through the creation of a Digital Health Centre of Competence and by building the necessary legal basis for agile regulation.

Inclusive Co-creation

Regulators, policymakers, and decision-makes should foster inclusive co-creation by engaging diverse stakeholders early on and providing guidance and standards to promote interoperability.

Value-driven Innovation

Decision-makers across the innovation ecosystem should support the adoption of value-driven innovation by monitoring the clinical use of innovations and prioritising innovations with social impact.

Capacity Building

Policymakers and decision-makers should drive capacity by promoting ethical awareness amongst all stakeholders and fostering regulatory knowledge and skills.

Explore the Roadmap online:
https://digitalhealthroadmap.ethz.ch

Content

Introduction

Switzerland stands at a crossroads in healthcare innovation. Renowned for its high-quality healthcare system and its prominent role in global pharmaceutical innovation, Switzerland faces a defining challenge in the realm of digital health: while it needs to catch up with other nations' adoption of established digital health solutions, the rapid emergence of new technologies such as artificial intelligence (AI) demands adequate responses to fill regulatory and governance gaps.

As it stands, the Swiss healthcare system has not yet fully embraced the digital revolution. Switzerland lags in core adoption cases such as teleconsultation, chronic patient remote monitoring, chronic disease self-management, and the implementation of electronic health records. As such, the country has significant untapped potential in digital healthcare, with projections indicating that a comprehensive digitalisation strategy could lead to substantial economic savings. An analysis shows that "the overall improvement potential in Swiss healthcare from fully implementing digitization possibilities available today is up to CHF 8.2 billion," representing 11.8% of the country's total addressable healthcare expenditures.[8]

To embrace healthcare innovation, Switzerland needs to adapt and establish new regulations. This is because rapid advancements and the disruptive nature of technologies such as AI-driven diagnostics, telemedicine, and personalised medicine, are reshaping the landscape in ways that existing regulations may struggle to address effectively. These innovations are not just incremental improvements but represent fundamental shifts in how healthcare is delivered and experienced. As such, they raise unique issues related to data privacy, ethical considerations in AI decision-making, and the regulation of digital health devices. More tailored and adaptive regulatory frameworks are needed to respond to the specific challenges of digital health technologies so as to ensure patient safety and efficacy while fostering innovation in healthcare.

Challenges of the current regulatory ecosystem

Wide-ranging implications
Innovation in healthcare can have far-reaching ethical and societal consequences. Since digitalisation spans a range of sectors and industries, regulation may stifle innovation.

The speed of innovation and regulatory uncertainty
The fast pace of technological development may result in regulatory gaps due to the slower pace of policy-making. This gap can create regulatory uncertainty, leaving new technologies and their deployment without clear guidance.

Limited international collaboration
Digital technologies often transcend national boundaries, creating a need for international regulatory cooperation and harmonisation. However, aligning regulations across different jurisdictions has proven to be a highly complex task.

Widening health disparities
While new technologies promise improved efficiency and effectiveness in healthcare delivery, there is an inherent risk that they could exacerbate existing inequalities. Access to advanced healthcare technologies may not be accessible to those with limited financial resources, thereby reinforcing a socio-economic divide in the quality of healthcare.

What this Roadmap seeks to achieve

The swift pace and the complexity of digital innovation demand that decision-makers continuously adapt to a changing technological landscape, engage with a broad range of stakeholders and anticipate future trends to create effective and responsive regulations. Against this backdrop, this Roadmap seeks to support decision-makers in promoting responsible digital health innovation, which has the following trickle-on effects.

Enable innovation
Equip Switzerland with an agile and adaptive regulatory ecosystem that enables innovation and harmonises with international regulatory standards.

Advance healthcare
Future-proof the Swiss healthcare system to harness the potential benefits of new technological transformations.

Boost economy
Remove roadblocks and legal uncertainties to facilitate domestic as well as cross-border synergies while attracting international investors.

Foster public trust
Ensure that the development and use of health innovations are safe, effective, and benefit patients and the public at large.

Governance principles

Agile Regulation

Agile regulation is an innovative approach to regulatory practices based on flexibility, iterative processes, an experimental mindset, and collaboration. By adopting an agile approach, policymakers, and other decision-makers can more effectively anticipate and manage fast-emerging, high-impact digital health innovation.

Consider medical wearables. Agile regulation would help regulators to quickly approve software and updates, thereby balancing innovation with safety.

Rationale

The rapid development of emerging technologies poses significant challenges to existing regulatory frameworks.[9] The swift pace of technological advancements often surpasses the speed at which regulations can be developed, thereby limiting their effectiveness in guiding innovations towards socially beneficial outcomes.[10] This regulatory lag creates uncertainty, which is not only challenging for small companies and start-ups but can, due to insufficient oversight, have severe consequences such as patient harm and increased healthcare costs. Specifically, regulatory uncertainty can result in the premature adoption of technologies that fail to meet essential safety, efficacy, and fairness standards. Conversely, it can also delay patients' access to potentially beneficial technologies or treatments.

An agile approach to regulation can help policymakers deal with the rapidly changing nature of technology. In particular, this approach enables actors to react swiftly to changes in the field, strategically direct resources to high-stake areas, test and validate various regulatory solutions, and more accurately evaluate how regulation affects innovation.[11-12] It can also help increase legal certainty by reducing the use of prescriptive, rule-based regulatory responses (e.g., laws and ordinances), which are less suited to highly dynamic technologies.[9,12-13]

What is needed

For Switzerland to successfully adopt and implement agile regulation, policymakers should:

#1 Create a Digital Health Centre of Competence.

#2 Build the necessary legal basis for agile regulation.

Action 1:

Create a Digital Health Centre of Competence

The need for a specialised governance body

To effectively monitor and assess advancements in the complex and rapidly evolving field of digital health innovation, governance actors need to rely on and draw upon domain-specific expertise. Regulators thus need a wide range of competencies, including a thorough understanding of how new technologies work and of the relevant ethical and legal frameworks that can be applied. Currently, such skills and knowledge are scattered across governance organisations in the digital health ecosystem, limiting efficient coordination and hindering collaboration and mutual learning between regulators and innovators. To tackle the challenges posed by fragmented regulatory capabilities in digital health, Switzerland should consider establishing a dedicated Digital Health Centre of Competence (DHCC).

The centre's purpose

The Digital Health Centre of Competence (DHCC) will have regulatory functions supporting digital health development and deployment. In particular, the centre will:

- **Support regulatory oversight:** The DHCC will strengthen existing regulatory activities by overseeing the licensing of digital medical devices, concentrating specific regulatory science expertise, collecting information from regulatory experimentation (Action 2), and offering technical and policy advice. Further, through the provision of resources and training opportunities (Action 8), the DHCC will enable regulators to engage with stakeholder groups (Action 3).

- **Empower stakeholders:** The DHCC will promote engagement between innovators and patient advocacy groups and healthcare providers early on so as to ensure their needs are integrated and addressed during technology development (Action 3). Innovators would be further supported through provisions of ethical and technical guidance that focuses on AI transparency, fairness, and bias mitigation (Action 7).

- **Set standards:** The DHCC will establish clear and consistent standards for pre-market evaluation and post-market surveillance of digital health technologies (Action 4).

- **Monitor regulatory requirements:** The DHCC will promote and monitor regulatory experiments (such as sandboxes (Action 2)) to determine the effectiveness of different regulatory approaches. Results and findings from these experiments can help the centre develop future policies and best practices.

Implementation

The following actions are needed for the establishment a Digital Health Centre of Competence (DHCC):

☐ **Develop a legal framework:** Policymakers can support the establishment of the centre by developing a legal framework. This framework should enable the centre to oversee the licensing of digital health tools (Action 2), and set standards for pre and post-market evaluation of technology effectiveness, alongside data quality and ethical implications. Adequate provisions should also be in place so that the centre can run and evaluate regulatory experiments (e.g. sandboxing) so as to inform future regulatory adaptations (Action 2).

☐ **Provide resources:** Policymakers should allocate financial resources and recruit skilled personnel to support the centre's ability to conduct iterative policy assessments and adaptations, as well as to engage with stakeholders.

☐ **Ensure diverse representation:** Policymakers should guarantee that diverse specialists work at the DHCC, including experts from AI, cybersecurity, data privacy, bioethics, and health law. The centre should also collaborate with university researchers, healthcare providers, industry professionals, and patient representatives.

Digital Health Competence Centre

A Digital Health Competence Centre would ensure that Switzerland has the right expertise, collaboration, and skills to implement agile regulation. By adopting an agile regulatory approach, Switzerland can be an international leader in health innovation, all the while safeguarding the interests of the public.

Action 2:

Build the necessary legal basis for agile regulation

The need for a legal basis

At present, all new federal regulations in Switzerland must undergo a thorough review of their potential impact (mandatory ex-ante regulatory impact assessment (RIA)). Only some regulations get re-evaluated (ex-post evaluation) to assess their impact and outcome. A legal foundation that enables regulatory experimentation and planned adaptation is needed to promote a more dynamic and adaptive regulatory environment.

Regulatory experimentation refers to the testing of products, services, or regulatory approaches in controlled environments before being widely implemented.[9] Such experimentation enables the identification of regulatory barriers, uncertainties, and any adaptations needed to mitigate risks (Action 6). Two common methods for such testing are regulatory sandboxes and pilot projects. Switzerland already utilises both approaches: for example, sandboxing is applied in the energy sector,[13] and the Federal Office of Public Health has established a framework for pilot projects.[14] These initiatives highlight Switzerland's preparedness for an adaptive regulatory approach.

Planned adaptation is another key element needed for agile regulation. It refers to systematically gathering information and assessing the impact of regulations, which enables timely updates based on evolving scientific knowledge and shifts in social, political, technological, and economic landscapes.[15] This approach facilitates gradual regulatory adjustments to accommodate changing conditions and rapidly advancing technologies.

Implementation

The following actions are needed to build the legal basis for agile regulation:

☐ **Assess current legislation:** Policymakers should evaluate whether existing sandboxing and piloting mechanisms can be applied to new digital health tools.

☐ **Develop and adapt regulations:** Policymakers should establish mechanisms to enable planned adaptation and regulatory experimentation in the governance of digital health innovation.

☐ **Early dialogue:** Regulatory bodies such as the DHCC should create mechanisms to engage with innovators early on and continuously throughout the innovation cycle.

☐ **Grant authority and oversight:** Policymakers should grant capacity to specific authorities, such as the Digital Health Centre of Competence (Action 1) to initiate, monitor and evaluate regulatory experiments (e.g. sandboxing) to inform future regulatory adaptations.

By establishing the legal base for agile regulation, Switzerland would be better able to navigate the challenges and harness the opportunities presented by rapidly evolving digital health technologies, all while ensuring that regulation remains aligned with societal needs and ethical principles.

Regulatory experimentation
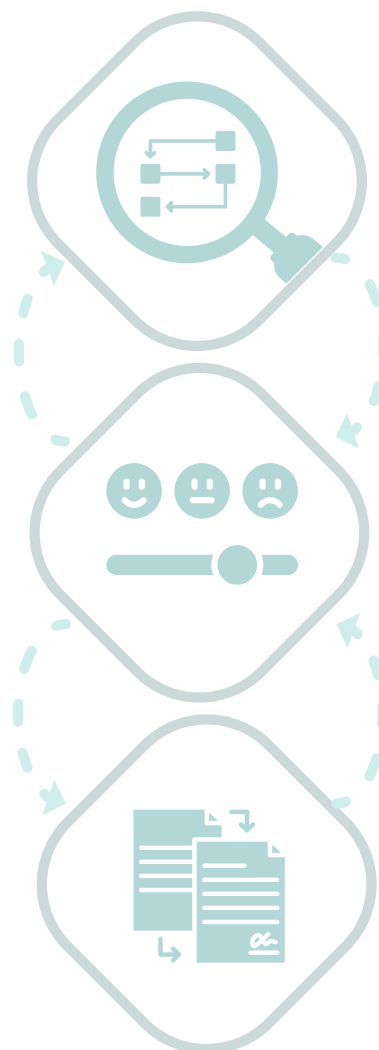
Regulators **experiment** in controlled settings to explore new policies and technologies.

Feedback is gathered from stakeholders to assess the impact and policy effectiveness.

Regulators **refine** policies based on evidence, reducing uncertainty and fostering innovation.

Inclusive Co-creation

Inclusive co-creation is the early and ongoing involvement of all relevant stakeholders in developing and deploying innovative technologies. This ensures collaboration, equitable representation, and shared ownership of innovation outcomes.

Consider a co-designed medical device. Inclusive co-creation would help to improve the user experience, safety, efficacy, patient acceptance, and accelerate time to market.

Rationale

Anticipating the societal impact of any given technology is particularly challenging in the earliest phases of new technology development and implementation; on the other hand, once technologies are mature and widely diffused, adapting them to societal needs and mitigating their side effects is costly and notoriously hard.[16]

Early engagement with stakeholders facilitates the identification of a broader array of needs and expectations around technologies and allows innovators to better anticipate the impact of their products and adapt technology design so as to minimise risks.

Co-creation is an approach to technology development that actively involves a broad set of stakeholders, including affected parties and end-users, seeking their input to create solutions that consider stakeholder needs. In Switzerland, the fragmentation of the healthcare system, characterized by various stakeholders and interdependent processes, makes it even more urgent to use co-creation such that digital health innovations are aligned with the expectations of end users such as healthcare professionals, are compatible with the capacities of payers, and serve the needs of patients.[1]

What is needed

For Switzerland to successfully adopt and practise inclusive co-creation, policymakers should:

#3 Engage diverse stakeholders.

#4 Provide guidance and standards.

Action 3:

Engage diverse stakeholders

The need for diverse stakeholder engagement
Inclusive co-creation is crucial to identify and develop a cohesive strategic vision for digital health innovation in Switzerland. An aligned vision encapsulates a shared understanding of societal priorities and ethical principles for digital health innovation.

Despite the benefits of co-creation and collaboration, many organisations fail to involve stakeholders early on in the development process. This can result in technologies that do not align with regulations or societal demands and that lack thorough evaluations of efficacy and user satisfaction. Early exchange among patient organisations, healthcare professionals and innovators can be facilitated by the Digital Health Centre of Competence (Action 1), leading in turn to the emergence of an aligned vision, including standards that are necessary for responsible innovation (Action 6). Early collaboration can also help ensure that high-risk and high-speed innovations receive early regulatory guidance. Furthermore, early collaboration can help smaller companies navigate complex regulatory landscapes and ensure their innovations meet the necessary standards.

Implementation
The following actions will help support effective stakeholder engagement in co-creation processes:

☐ **Include all stakeholders in regulatory experimentation:** Policymakers should promote experimentation that involves a broad range of stakeholders, including patients and healthcare professionals. Sandboxing (Action 2) can facilitate this by providing a controlled environment for testing new technologies with diverse user groups.

☐ **Prioritise impactful technologies:** Policymakers should establish priority review mechanisms for technologies expected to have a significant impact on patient outcomes or that address unmet medical needs (Action 6).

☐ **Ensure equitable access:** Policymakers should ensure that all entities (small and large) have equal access to early exchanges, priority review, and pilot projects.

☐ **Enable exchanges:** Policymakers should improve data sharing and interoperability by supporting the evolution of technical standards. Regulators should also provide clear guidance on product development and testing to streamline innovation and facilitate inclusive co-creation (Action 4).

Engaging diverse stakeholders will help to ensure that innovation in digital health aligns with societal needs and users' expectations. This will help facilitate technology adoption and will improve patient outcomes.

Key stakeholders in the digital health ecosystem

Innovators
develop novel innovations in digital health and medical AI (e.g., Starups and Pharma).

Regulators
oversee innovation, enforce laws, and ensure compliance (e.g., Policymakers).

Implementers
adopt digital tools in health-care settings (e.g., Hospitals and healthcare practioniers).

End-users
use digital tools for health-care purposes (e.g. patients, citizens, and caretakers).

Action 4:

Provide standards

The need for standards and interoperability

Interoperability issues stemming from the diverse and interdependent nature of Switzerland's healthcare system are major obstacles to co-creation activities in healthcare. A vital aspect of cross-stakeholder collaboration in digital health is the sharing of medical and non-medical data. Lack of interoperability standards, for instance, has been shown to considerably hinder data sharing and slow down collaboration across sectors and institutions.[1]

The establishment of uniform standards will improve interoperability and ease multi-stakeholder co-creation. Specifically, standardised terminology and processes can help to streamline operations, reduce misunderstandings, increase the overall efficiency of operations, and create a better environment for collaborative innovation (Action 3). Furthermore, by ensuring that ethical issues like privacy, openness, and fairness are consistently and correctly addressed across all platforms and applications, standards contribute to the growth of public trust in digital health technology.
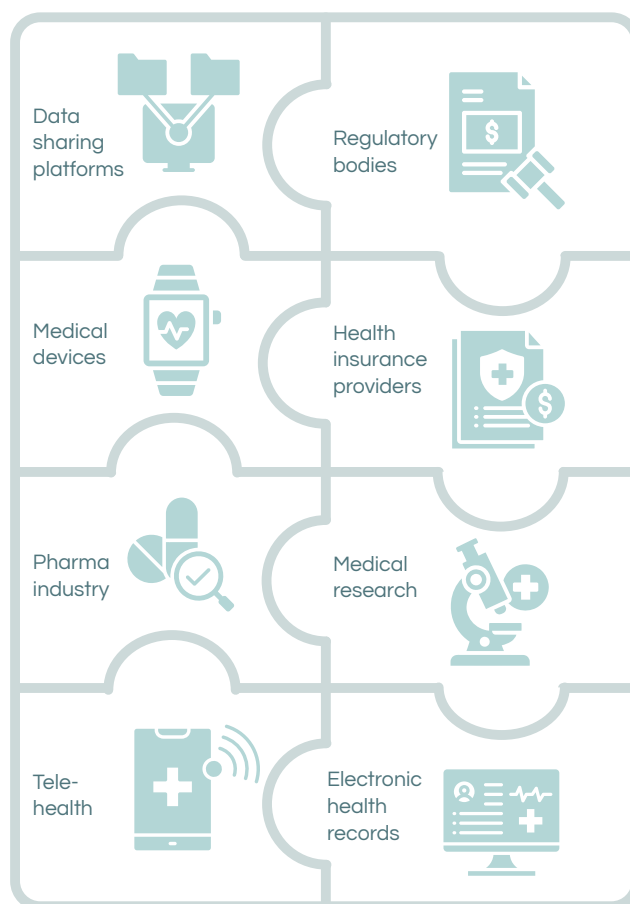
Implementation

The following strategies should be implemented to promote interoperability, and ultimately enable co-creation:

☐ **Provide tailored guidelines:** Regulators should issue guidelines that help homogenise technology development, such as tailored regulatory guidance specific to medical specialities (e.g., radiology, ophthalmology, and dermatology) that considers the different intended use of the technology (diagnosis, prognosis, treatment, monitoring, clinical workflow, or administration).

☐ **Leverage existing initiatives:** Policymakers should foster the use of existing initiatives and secure data-sharing platforms. As an example, the Swiss Personalized Health Network (SPHN) has achieved notable strides in the governance and standards of data access and exchange.

☐ **Adopt existing standards:** Policymakers should actively encourage the adoption of established standards (Action 2), such as the IEEE7000 standard for innovators from the Institute of Electrical and Electronics.[17-18] This standard addresses ethical concerns related to system design, promotes openness and supports innovation based on values.

☐ **Incentivise usage:** Regulators should actively promote and incentivise using uniform standards, for instance by rewarding organisations that adhere to emerging standards in terms of access to priority review mechanisms.

Switzerland can facilitate stakeholder collaboration and interoperability in the digital health ecosystem by establishing consistent, uniform standards, and by providing guidelines for innovators. This will further help to guarantee that innovations are tailored to meet the needs of regulators and policymakers.

Key areas of the healthcare ecosystem

Data sharing platforms

Regulatory bodies

Medical devices

Health insurance providers

Pharma industry

Medical research

Tele-health

Electronic health records

Value-driven Innovation

Value-driven innovation refers to aligning innovative technologies with their intended societal benefit by adopting best practices that capture, incorporate, and promote societal needs and user values.
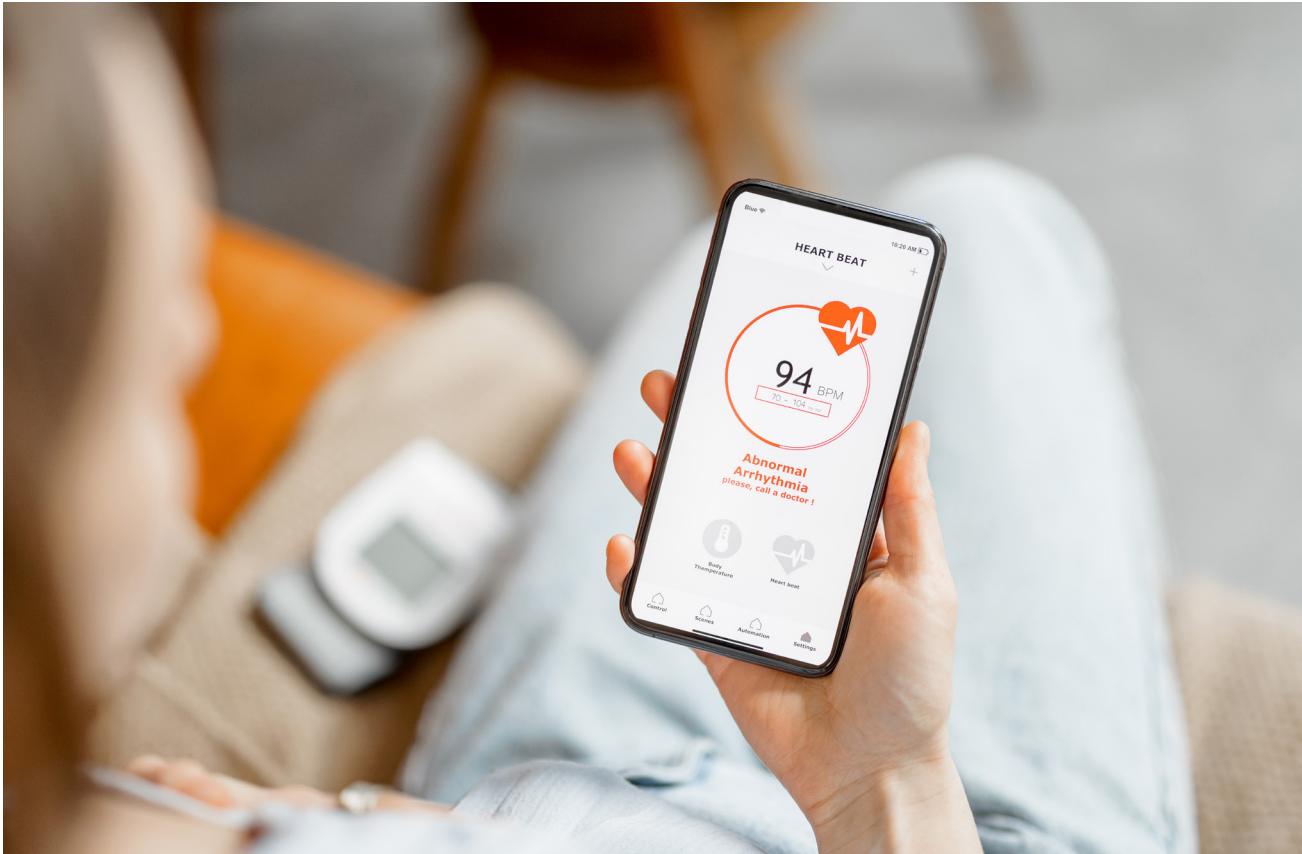
Consider a blood pressure monitoring app. Value-driven innovation would help ensure this app is usable and affordable for all.

Rationale

Innovators often focus on optimising new technologies for efficiency and accuracy while paying less attention to societal contexts and users' values. However, to promote and ensure societal benefit, technology should be anchored in the values and priorities of the people it serves: healthcare professionals, administrators, and patients.[19]

Further, the rapid development of technologies like Machine Learning (ML) and Large Language Models (LLMs) can force adaptation by healthcare systems and induce actors to recalibrate and reassess their expectations accordingly. Societal values should shape the pace of innovation uptake, determining the conditions for its emergence, how rapidly it spreads, and how technology meets the expectations of its intended users. Value-driven innovation is an approach to technology implementation that takes such complex dynamics into account and channels technology impact in socially desirable ways.

In Switzerland, value-driven innovation holds promise to promote digital health technologies that address the country's specific healthcare needs. This includes managing rising costs, introducing automation to streamline workflows, compensating for the systemic shortage of medical doctors and other health care personnel, improving access to and exchange of patient information between service providers and health authorities, improving integrated care, and boosting efforts to address preventable risk factors.[20]

What is needed

For Switzerland to promote a value-driven approach to digital health, decision-makers across the innovation ecosystem should:

#5 Monitor clinical use.

#6 Prioritise innovation with social impact.

Action 5:

Monitor clinical use

The need to monitor use and impact

The implementation of digital health innovation in the Swiss healthcare system could have relevant ethical and societal implications. Examples include privacy and data protection issues, the risk of bias worsening health inequalities, and the lack of transparency in automated decision-making processes. In the case of AI, many systems lack transparency, which makes fairness assessment challenging in terms of model performance and its impact on patient health, quality of life, disease progression, and mortality. Additional challenges relate to liability, managing adaptive and evolving technologies (such as continual learning AI systems), and the potential impacts on healthcare expenditures and patient-doctor relationships.

To ensure value-driven innovation that meets the needs of the Swiss public and healthcare system, attention must be paid not only to technology development, but also to what happens after a digital health tool enters clinical use. Therefore, health centres must rigorously monitor implementation and clinical impact, which encompasses comprehensive technology assessment and the evaluation of clinical outcomes, access to care, and the satisfaction of patients and healthcare personnel.

Implementation

To effectively implement value-driven innovation, decision-makers in the healthcare ecosystem should:

☐ **Establish oversight roles:** Clinical centres must designate roles for coordinating, assessing, and monitoring the implementation of digital health innovations. In the case of AI, large clinical centres (public and private) should appoint a Clinical AI Officer, while smaller centres and individual practices may rely on a local AI Officer to fulfil the same functions.

☐ **Train health personnel:** Healthcare personnel should receive adequate training on how to use digital health technologies to ensure effective and responsible implementation in clinics (Action 7). Clinical centres should further ensure training programs are updated regularly to reflect changes in digital health technologies.

☐ **Monitor digital health systems:** Clinical centres should monitor the deployment of digital health innovations across all medical specialities and clinical tasks, including diagnosis, prognosis, and treatment allocation. This monitoring should assess clinical performance and broader impacts on health outcomes and access to care. Clinical AI Officers can coordinate such activity. Automation can also be used to document impact so as to improve efficiency and facilitate oversight.

☐ **Collaborate:** Clinical centres should liaise with technology providers to ensure sufficient technical documentation (including a system's limitations), auditability, continued support, and the ability to customise digital health solutions to specific clinical needs. Joint decisions between clinical centres and ethics committees are also crucial when innovations have ethical implications, such as when AI is employed.

☐ **Setup technical safeguards:** Clinical centres should employ appropriate measures to assess and promote transparency and fairness for AI systems. This includes using state-of-the-art bias mitigation techniques and explainability methods.[21-22]

☐ **Share monitoring results:** Clinical AI Officers should share the results of their monitoring activities with relevant stakeholders, including regulators, researchers, patients, and other healthcare providers. This can help identify trends, best practices, and areas for improvement in using digital health technologies.

By adopting adequate monitoring strategies, Switzerland can ensure that the implementation of new digital health innovations will enhance the quality of care and serve the needs of patients, providers, and society.

Aspects that should be monitored

Access to care

Is the innovation...

- Accessible?
- Availible in a timely manner?
- Affordable to all patients?

Clinical outcomes

Is the innovation...

- Effective?
- Safe, with risks managed?
- Improving quality of life?

Patient / doctor satisfaction

Are the end users...

- Satisfied with their care?
- Satisfied with the treatement process?

Action 6:

Prioritise innovation with social impact

The need to prioritise social impact

How to ensure that technologies meet societal needs remains a subject of debate. Some believe that innovation, despite its disruptive potential, will ultimately lead to positive societal outcomes. Others are instead concerned that market-driven technology development does not naturally align with societal needs and may even be harmful.

To ensure that technological advancements align with societal needs, stakeholders must develop a shared vision of desirable outcomes. Policymakers play a crucial role in this process by facilitating inclusive deliberations. Through these discussions, they can gather diverse perspectives on how technology can effectively address pressing issues and overcome barriers to social progress, justice, and resource efficiency.

By integrating public perspectives into decision-making processes, policymakers can foster technological outcomes that are socially beneficial and garner broad public trust and support. In the context of rapidly advancing technologies like AI, this approach provides an opportunity to deliberately enhance the social value of technological progress while simultaneously raising awareness about its potential implications.

Implementation

The following actions should be implemented to help promote innovation with social impact:

☐ **Prioritise impact:** Policymakers, in collaboration with stakeholders, should identify and prioritise areas where digital health innovation is most likely to have a significant positive impact on society, such as when innovation improves safety, reduces health inequalities, and contains healthcare costs.

☐ **Foster dialogue:** Policymakers and regulators should actively foster public dialogue with and amongst stakeholders through the Digital Health Centre of Competence (Action 1). Other options include establishing dedicated units staffed with public engagement experts and involving diverse stakeholders, such as patients, healthcare professionals, innovators, ethicists, payers, funders, and investors (Action 3).

☐ **Align the vision:** Policymakers should enable responsible bodies, such as the Digital Health Centre of Competence (Action 1), to define and promote an aligned vision for digital health innovation. This vision should prioritise areas with higher impact based on insights from dedicated public engagement events involving patients, innovators, and citizens.

☐ **Base funding decisions on aligned values:** Policymakers should encourage public and private funding agencies, as well as investors, to base their funding decisions on

an aligned vision, thereby prioritising innovations deemed to have significant societal benefits.

Switzerland can steer innovation towards beneficial outcomes and address societal needs by fostering public dialogue, gathering insights, and aligning decision-making with agreed-upon shared values.

Three areas of social impact

Personalised care — Data efficiency — Remote monitoring — **Health System** — Accurate diagnosis

Wider access — Online support — Patient involvement — **Society** — Economic growth

Disease tracking — Informed decisions — Global health initiatives — **Public Health** — Coordinated disaster response

Capacity Building

Capacity building refers to improving a stakeholder's ability to understand, evaluate, and effectively participate in the development, implementation and governance of digital health technologies.

Consider trainings to promote digital literacy for citizens, patients, and doctors. This capacity building would help promote better patient-care and transparency for all.

Rationale

To foster a responsible innovation ecosystem in digital health, built on agile regulation, co-creation, and value-driven innovation, stakeholders should have a common language and skill set. Continuous enhancement and updating of these capacities are crucial for addressing technical complexity and navigating ethical concerns, regulations, and governance practices.

Currently, stakeholders in the digital health ecosystem face significant challenges in keeping up with and adapting to digital health innovations. Regulators often have an insufficient understanding of digital health technology, lack agile process skills, and are relatively inexperienced in the use of regulatory technologies (RegTech). For the development of safe and ethically sound technology, innovators should be sufficiently aware of ethical risks and should seek to acquire the skills to implement ethical technology. Moreover, to safely use digital health technology in the treatment of patients, healthcare personnel should have a thorough understanding of the workings of the technology and its risks. Similarly, patients should develop a minimum level of understanding of technology and digital ethics literacy to partake in co-creation and assess technology uses and their ethical challenges.

What is needed

The following actions are required to diffuse the necessary skills and capacities across the stakeholders in the digital health ecosystem:

#7 Promote ethical awareness.

#8 Enable regulatory innovation.

Action 7:

Promote ethical awareness

The need for ethical awareness

Ethical awareness is an important part of responsible innovation as it helps ensure positive societal outcomes and allows for the early identification and mitigation of ethical issues that can arise throughout the technology development process and its implementation. However, at present, the level of ethical awareness is low among innovators in Switzerland, representing a critical obstacle to stakeholder collaboration in digital health innovation.[1]

Stakeholders need to have a better understanding of how digital technologies operate and the environments in which they will be deployed. An insufficient grasp of the technology and a lack of context sensitivity can inhibit a stakeholder's anticipation and mitigation of ethical issues that can arise. For example, healthcare professionals require a comprehensive understanding of technology to ensure its safe and equitable use. Similarly, patients should possess a basic understanding of how technology functions to engage meaningfully in shared decision-making and co-creation processes, advocate for their needs, and contribute to technology assessments. Not only does this help them assess ethical concerns related to health data uses and the information provided by the tool, but it also can help patients feel empowered to "have a seat at the table" and participate in inclusive dialogues and exchanges about their needs and preferences.
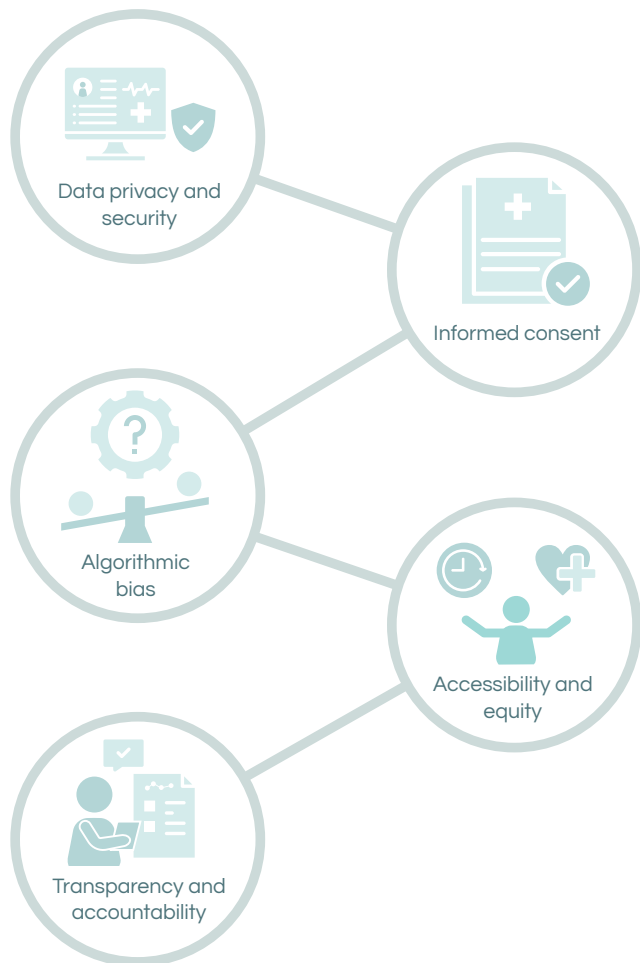
Implementation

The following actions will help support fostering ethical awareness across stakeholders in the digital health ecosystem:

☐ **Disseminate information:** Policymakers should encourage regulators, innovators, and healthcare providers to disseminate important technical information and ethical considerations related to digital health technologies and their use. This could take the form of ethics impact assessments.[23]

☐ **Promote best practices:** Regulators should encourage the adoption of best practices to enable innovators to better address ethics in digital health innovation and incentivise innovator adherence in the regulatory approval process.

☐ **Fund research:** Policymakers should support the allocation of resources to conduct and disseminate research on ethical risks and best practices to address them. These insights can inform stakeholder efforts to help them manage emerging ethical concerns.

☐ **Train staff:** Medical schools and health centres should provide their employees with the education and training they need to recognise and address ethical concerns when utilising digital health technologies.

By promoting a shared understanding of the ethical issues and context sensitivity, Switzerland can ensure the responsible development and deployment of digital health technologies.

Ethical issues and challenges

Data privacy and security

Informed consent

Algorithmic bias

Accessibility and equity

Transparency and accountability

Action 8:
Foster regulatory knowledge

The need for regulatory knowledge

To effectively exchange information with stakeholders and regulate new digital health technologies, regulators must be up to date about developments in other jurisdictions and possess a solid understanding of technology and tools to streamline the regulatory process.

Regulatory knowledge also includes knowing what tools can help support regulatory processes, such as assessing and verifying regulatory compliance. Two key groups of technological tools, supervisory technology (SupTech) and regulatory technology (RegTech), have emerged to help address regulatory bottlenecks and support co-creation. SupTech refers to advanced computational applications that assist regulators in activities such as monitoring, overseeing, and regulating partially automating the detection of risks with real-time insights. RegTech refers to advanced computational applications that help innovators comply with regulations, resulting in data-driven insights for risk assessment, reduced costs, and timely responses to regulations. In addition, RegTech is valuable in unpredictable contexts as it drives standardisation, streamlining and automation of key processes.[24] Both RegTech and SupTech can improve the efficiency of regulatory operations whilst also providing high-quality data-driven insights.

AI holds promise to help with regulatory processes. Machine learning (ML) and Large Language Models (LLMs), for instance, can speed up and improve the accuracy of document processing. Regulators should thus take a proactive role in the creation and application of new tools aimed at enhancing regulatory procedures. To achieve this, they should further build and strengthen their expertise in technical domains, such as through expanding the scope of work of innovation labs like, for example, "Swissmedic 4.0."

Despite the promises of these new tools and the need to promote capacity in the Swiss digital health ecosystem, significant investments are required on behalf of organisations and individuals to adopt such instruments. Organisations need to invest financial resources and may face organisational inertia in adopting new processes and tools. Similarly, individuals have to invest significant time and effort to acquire relevant capacities in relation to such new tools.

Implementation

The following actions will help promote regulatory knowledge amongst digital health stakeholders:

☐ **Provide funds:** Policymakers should create digital healthcare upskilling funds to incentivise capacity-building in innovative areas of regulation.

☐ **Share knowledge:** Regulators should be well informed about current trends and best practices for digital product development, regulatory science, and international regulatory affairs.

☐ **Use and develop new tools:** Policymakers should support the use of current and new supervisory (SupTech) and regulatory (RegTech) technologies by regulators and innovators to streamline regulatory processes.

☐ **Strengthen skills:** Regulators and funding bodies should incentivise and support digital health stakeholders in acquiring the skills for effective collaboration with regard to new regulatory technologies.

Developing regulators' skills and knowledge, alongside the adoption of new tools and technologies, will create an agile regulatory environment that can effectively govern and support digital health innovation.

Regulatory and supervisory tools
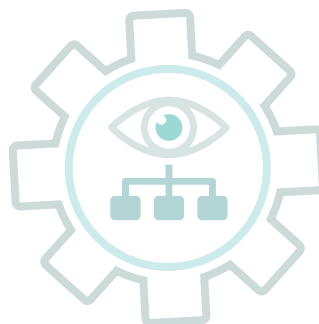
SupTech:
Using technology for regulatory, supervisory, and oversight purposes.

RegTech:
Using technology to manage regulatory processes to promote simplicity, efficiency, and cost-effectiveness.

Glossary

Artificial intelligence
"The capability of computer systems or algorithms to imitate intelligent human behaviour."[25]

Continual learning
A machine learning paradigm where models can adapt to new data without forgetting previously learned concepts. This is crucial for scenarios where data distributions change over time, such as real-world applications with evolving environments or data streams.[26]

Decision-makers
A person, group or entity that is responsible for making choices or setting strategies, usually after considering different options, available information and possible outcomes. Decision-makers act on the basis of objectives and values, set priorities and affect the courses of action in professional and organisational contexts.

Digital health ecosystem
The ecosystem is made up of various stakeholders, such as innovators, regulators, implementers, and end-users.

Governance principles
Action-guides that indicate what needs to be done to achieve certain desirable governance outcomes.
- Governance principles specify governance objectives and spell out the means to achieve them.
- Governance principles are directed to specific actors who have the capacity and the responsibility to follow them in practice.
- A set of governance principles for a specific policy domain constitutes a governance framework for that domain.

Integrated care
Integrated care systems (ICSs) are local partnerships that bring health and care organisations together to develop shared plans and joined-up services. Their aim is to improve health and care services – with a focus on prevention, better outcomes and reducing health inequalities.[32]

Interoperability
Interoperability means different systems can work together smoothly. For data, it ensures data from various sources can be integrated, shared, and analysed seamlessly. There are two main challenges: semantic interoperability (meaning of data) and technical interoperability (formats, standards, processing). Overcoming these is key for extracting value from large datasets.[27]

Priority review mechanism
Programs that fast track and expedite the review process for drugs or technologies that are expected to have a great impact on a treatment's safety or efficacy compared to standard applications.[28]

Policymakers
People who create and enforce policies; allocate public funding, and occasionally guide or instruct law enforcement.[3]

Regulators
Developing laws and policies, monitoring innovators and enforcing laws.

Regulatory uncertainty
"Individuals' inability to predict the future state of the regulatory environment" due to a lack of clear regulations, guidelines, or standards.[29]

Regulatory affairs
"Ensures that companies meet international regulatory standards, enabling global product distribution and promoting international collaboration in a complex marketplace".[30]

Regulatory experimentation
Refers to the testing of products, services, or regulatory approaches in controlled environments before being widely implemented.[9]

Regulatory sandboxes
A type of regulatory experimentation. Regulatory sandboxes provide a controlled environment for testing innovative technologies for which standards and guidance still do not exist.[31]

Regulatory science
A multidisciplinary field that ensures the safety, efficacy, and quality of products within regulated industries, including pharmaceuticals, medical devices, biotechnology, cosmetics, and food.[30]

Responsible digital health innovation
Responsible digital health is defined as "any intentional systematic effort designed to increase the likelihood of a digital health technology developed through ethical decision-making, being socially responsible and aligned with the values and well-being of those impacted by it."[7]

System design
This refers to the underlying structure, components, and interactions that make up a technological system. For example, hardware components (processor, memory, screen), software (operating system, apps), and how they interact to perform various functions.[33]

Technology complexity
"The existence of many interdependent variables in a given system, where more variables and higher interdependence mean greater complexity and uncertainty. Complexity is subjective (Dorner, 1996)."[34]

Technological uncertainty
"Uncertainty on the part of the regulator that involves a lack of technological or scientific understanding of a specific type of product and its use in the human body. This definition of technological uncertainty is, by its nature, comprised of both uncertainty about how a product works as well as uncertainty about how the regulator will know that a new product works."[35]

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