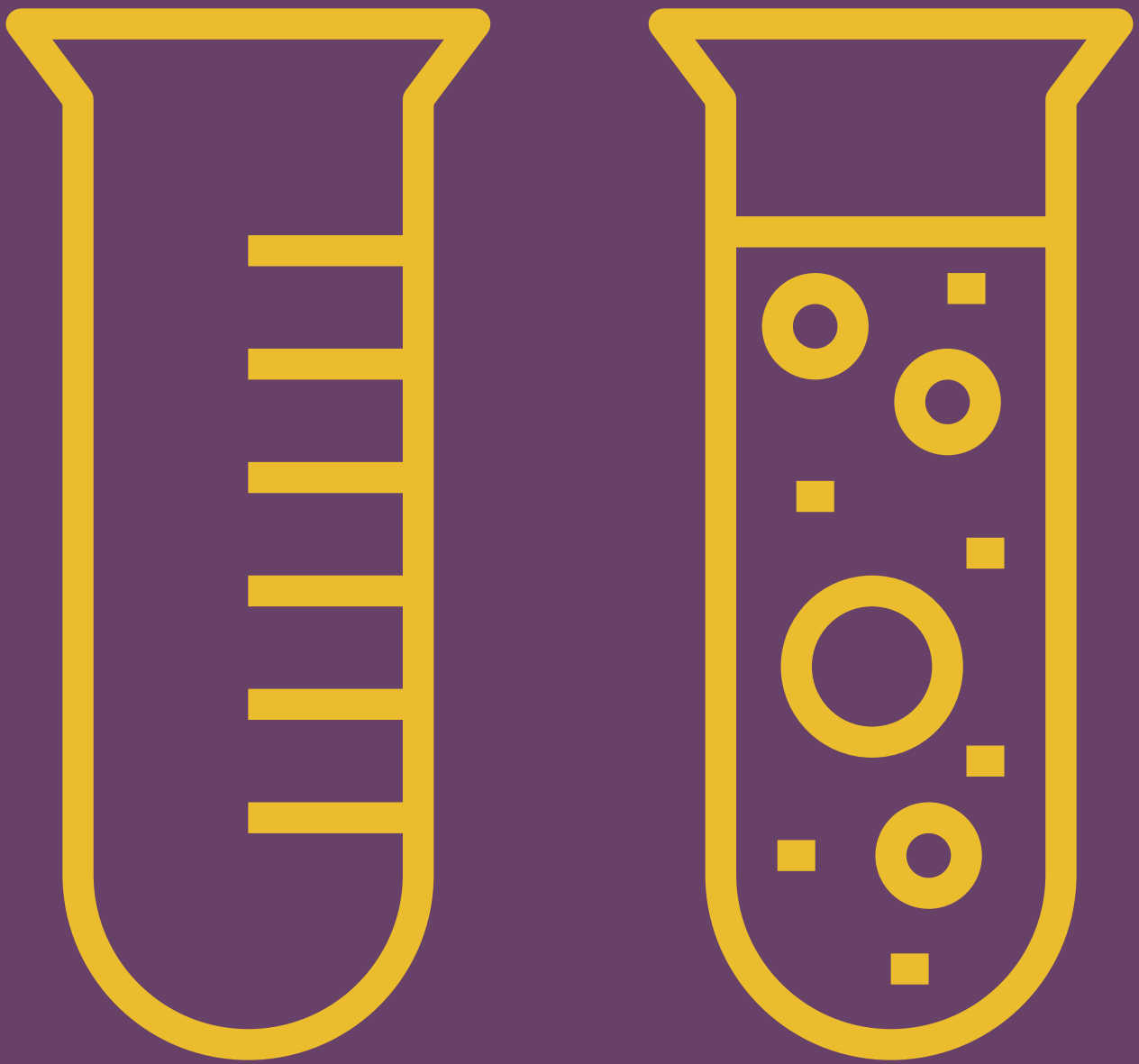
interpharma:ph

Success factor clinical research

Roadmap for a future-proof research location



Abstract

Switzerland is a small but prosperous country with limited natural resources and is therefore heavily reliant on trade and services. Clinical research not only provides Swiss patients with access to innovative medicines and improves the quality of care but also contributes to value creation and secures jobs. In addition, clinical trials generate added value for hospitals by increasing treatment quality, research activities and the attractiveness of training up specialists.

In view of increasing international competition in the life sciences sector, it is all the more important to strengthen clinical research in Switzerland. When it comes to choosing a location for clinical trials, Switzerland stands out for its high quality and efficient and transparent processes. However, it appears that the number of clinical trials in Switzerland is steadily declining. As the requirements placed on clinical research become increasingly complex, it is vital that Switzerland make a significant effort to become a future-proof location for clinical research. To do justice to its complexity and importance, clinical research must be enshrined as a key pillar of the healthcare system. It is incumbent upon policymakers, authorities, hospitals and industry to strengthen Switzerland's position as a location for clinical research and ensure the country's competitiveness on the international stage.

Interpharma
Association of Switzerland's research-based pharmaceutical industry
Petersgraben 35, Postfach, 4009 Basel, Switzerland
Telephone: +41 (0)61 264 34 00
Email: info@interpharma.ch
Website: www.interpharma.ch

In collaboration with Deloitte (Alexander Mirow, Kevin Schmid, Konstantin Ries, Jana Sailer)

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Pharmaceutical development is underpinned by clinical trials

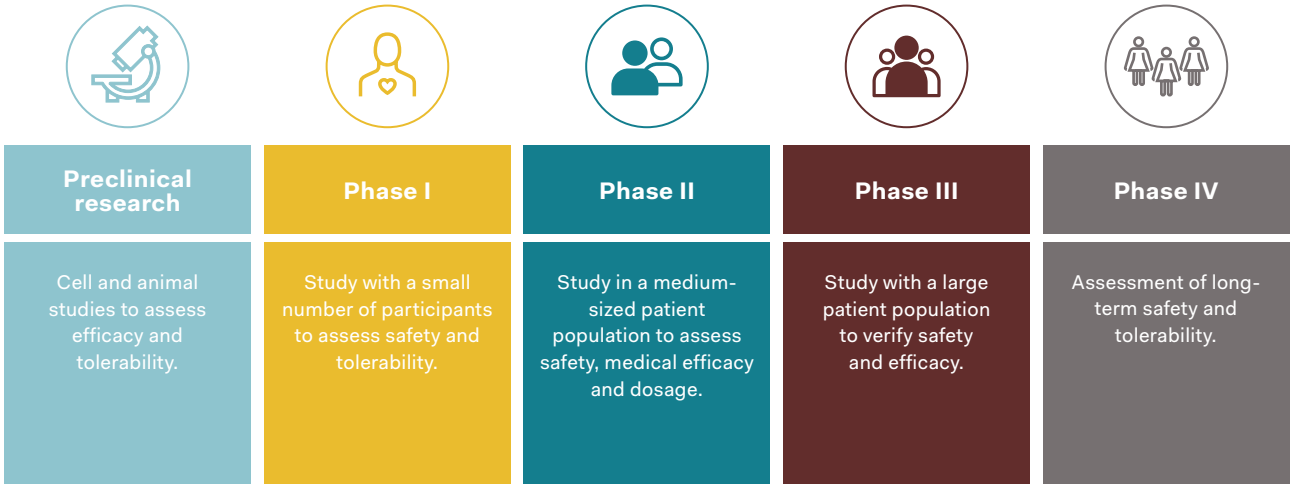
A few years ago, being diagnosed with hepatitis C meant living with a chronic disease and serious long-term consequences such as cirrhosis of the liver or liver cancer. The few treatments available were lengthy, stressful and often limited in their effectiveness. In 2013, a medical breakthrough was achieved thanks to innovative pharmaceutical research. New antiviral drugs, which usually only need to be taken in tablet form for a few weeks, completely eliminate the virus in 95% of cases.[1] Medical breakthroughs of this kind would not be possible without pharmaceutical research.

Pharmaceutical research not only improves our health and quality of life but also boosts the performance of our economy. At the same time, the requirements placed on pharmaceutical research are considerable. Before a drug is made available to patients, it must undergo rigorous testing to ensure its safety and efficacy.

The assessment of a new treatment's safety and efficacy is broken down into different phases – specifically, the preclinical phase and clinical trials (Phases I–IV) (Figure 1). In the preclinical phase, the safety of promising active substances for a specific condition is first tested on cells and in animal studies. This is followed by the four phases of clinical trials that are at the heart of every major drug innovation. During these phases, specially trained medical professionals assess and verify tolerability, efficacy and dosage with an increasingly large patient population. These patients have often had no or only insufficient opportunities to be treated beforehand, and they participate in the trials voluntarily. The trials also investigate long-term effects and rare side effects. Only when it has been ensured that a drug is safe and effective can it be placed on the market and made available to the general public. However, this is only the case for one in 10 of all active substances tested in clinical trials. As the driving force behind medical innovations, clinical trials provide patients around the world with hope for new treatments.

Pharmaceutical research for the development of innovative drugs

Figure 1



Drug development is subject to important regulations regarding the process, documentation obligations, and requirements relating to its results. Development is therefore a complex process requiring significant investment. It often takes 10 to 12 years from the initial idea to the market launch of a new drug, during which time extensive scientific and clinical studies must be carried out to assess the drug's tolerability, safety and efficacy.

In recent years, clinical trials and their implementation have become increasingly complex. The reasons for this include:[2, 3, 4]

- More complex forms of treatment, or personalized medicine
- Digital technologies, e.g. remote monitoring and electronic data collection and associated new technical standards
- New study concepts, e.g. the testing of drugs in conjunction with medical devices
- A greater number of stakeholders involved
- Greater regulatory requirements due to increased complexity of clinical trials

Countries such as Switzerland must face up to these challenges – individually or jointly – and create attractive framework conditions in order to address the emerging complexity, allowing them to compete internationally as a location for clinical research. ph

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There are advantages to carrying out clinical trials in Switzerland

The need for patients taking part in clinical trials to be as diverse as possible means that trials are carried out in numerous countries in parallel, and Switzerland therefore faces international competition. Carrying out clinical trials within its own borders is an important factor in Switzerland's success as a globally renowned research location. Indeed, clinical research is a key component of Switzerland's success in the field of medicine, with its renowned hospitals, high standards of care, first-class researchers and tradition of scientific excellence. This is directly beneficial to patients in Switzerland, who often have the opportunity to receive life-saving treatments before they are generally available. At the same time, carrying out clinical research adds significant economic value and strengthens Switzerland's position as a global center for life sciences and pharmaceutical innovation.[5] Clinical research is a key driver of medical innovation and makes a measurable contribution to a country's economic and social development. Every year, the research-based pharmaceutical companies invest around CHF 9 billion in research and development (R&D) in Switzerland – over 70 % more than they earn in the country. The sector therefore makes up the largest share, at 37 %, of private-sector spending in R&D.[6] Studies in the UK, Austria, Italy and New Zealand show that private sector investment in clinical research delivers social and economic benefits: clinical research improves a location's competitiveness, promotes high-quality employment, contributes to improved healthcare and leads to cost savings in the healthcare system. Patients benefit from earlier access to innovative therapies, the economy is strengthened with billions in GDP and thousands of jobs, and the burden on the healthcare system is reduced thanks to additional revenue and better treatment outcomes.[7, 8, 9, 10] ph

Previously incurable diseases become treatable

Innovative drugs pave the way for longer lives. Diseases that were considered incurable a few years ago now mean only minor health limitations or can even be cured completely.

Care is improved

Innovative drugs pave the way for milder disease progression and improved prognoses. Research hospitals have lower mortality rates and often have better-trained staff.[6, 18]

Treatment quality increases

Doctors and nurses improve their own skills by participating in clinical trials – and their improved skills have a positive impact on their medical environment.[12]

System resilience increases

With a strong research ecosystem, the healthcare system is better prepared for future pandemics. During the COVID-19 pandemic, clinical research played a key role in the rapid development and authorization of vaccines.[13, 15]

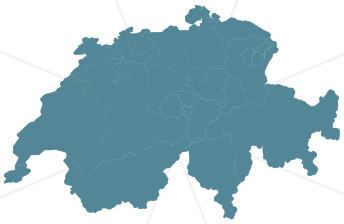
Specialists and talent are attracted and retained

A research-friendly healthcare system attracts qualified researchers. Integrating clinical research into hospital operations reduces brain drain.[6, 11, 17]

Patients get early access to innovative therapies

Study participants often gain access to new treatment options years before marketing authorization – particularly in the case of rare or serious diseases for which there is no other treatment option.[6, 11, 12, 15, 16]

Societal benefits



Economic benefits

Highly qualified jobs are created

Clinical research generates stable and knowledge-intensive employment in the healthcare and pharmaceutical sectors. These jobs are essential for economic development and secure a key locational advantage in the long term.[6, 15]

Public and private stakeholders work together

Collaboration between universities, industry and government – for example through public-private partnerships – promotes the transfer of scientific knowledge into practice.[13, 15]

Gross value added increases

Clinical research boosts gross domestic product (GDP) through direct economic contributions. In Switzerland, the pharmaceutical industry is one of the most important sectors of the economy, accounting for 5.4 % of GDP.[15]

Public finances benefit

Tax revenues from people and companies in the pharmaceutical industry go toward the budget and help to fund existing healthcare costs. Every Swiss franc invested in clinical research can generate almost twice as much value for the economy.[15]

Innovation and competitiveness are favored

Clinical research creates an attractive environment for investment and improves competitiveness on the international stage. Countries with efficient regulations have been able to consolidate their position as a leading location and promote investment.[13]

The burden on social welfare systems is reduced

Fewer sickness-related absences reduce expenditure on unemployment and disability insurance. A quicker return to work boosts economic productivity.[6]

Healthcare and care costs fall

Modern therapies reduce the need for long-term care and reduce the likelihood of expensive chronic disease progression. This leads to lower care costs and reduces the burden on the healthcare system.[6]

3

Switzerland is losing ground as a location for clinical research

Between 2018 and 2023, there was a significant increase in the number of clinical trials around the world – from some 18,000 in 2018 to over 22,000 in 2023 (a 22 % increase).[13] Global activity peaked at over 27,000 studies in 2021. Despite this global dynamic, however, Switzerland has quietly lost ground in recent years, with the number of clinical trials conducted in the country falling from 176 in 2018 to 149 in 2023 (a 15 % reduction).[18] This means that more and more clinical trials are carried out without patients from Switzerland and that fewer and fewer Swiss health professionals are involved in the clinical development of new drugs.

Recent years have seen a geographical shift in clinical research – primarily toward Asia. In particular, China has significantly expanded its position: having doubled its number of clinical trials since 2018, the country now holds around 29 % of the global share.[13, 14] As a result, Asia is increasingly becoming a preferred location for global trial activity (Figure 2-A). Particularly in terms of private-sector clinical trials that were carried out in only one country, China and the US were the main winners in 2023, achieving a share of over 50 %, as they stand out from smaller countries thanks to their very large and diverse patient populations.[13]

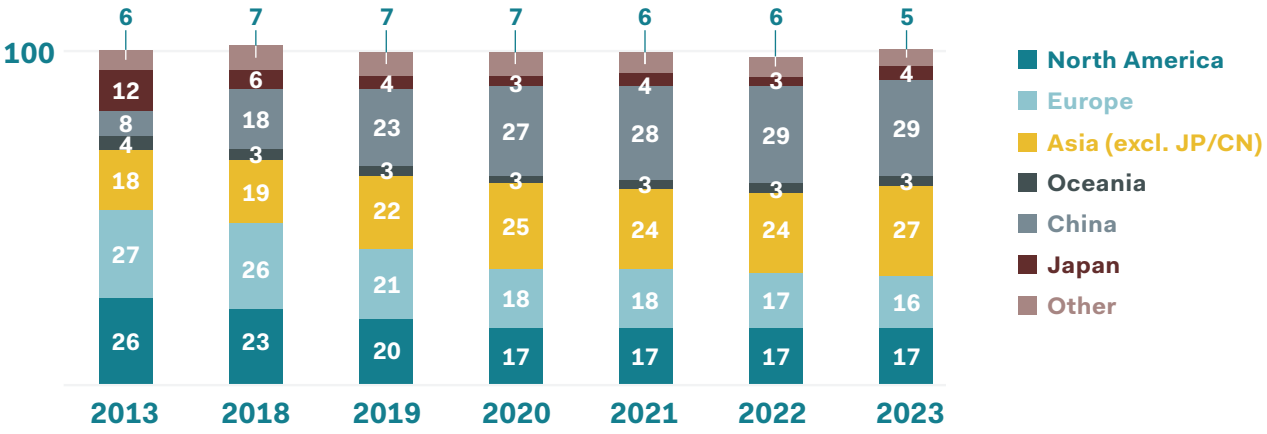
Meanwhile, European countries have experienced a significant loss of market share for clinical trials – from 27 % in 2013 to just 16 % in 2023.[13] Longer approval times and fragmentation of decision-making processes within Europe are making it increasingly difficult to initiate and carry out clinical trials efficiently. There are, however, clear differences across Europe. While the number of clinical trials has increased in countries such as Spain, Italy and Denmark, Switzerland is now below the 2010 level (Figure 2-B).

The change in the number of clinical trials has been accompanied by a significant increase in global investment in research and development (R&D) (Figure 3). R&D spending by the world's 20 largest pharmaceutical companies increased by almost 50 % from USD 108 billion in 2018 to USD 161 billion in 2023. This steady increase in investment reflects growing demand for innovative therapeutic approaches and illustrates the fact that global competition for clinical research locations has intensified. These investments are not, however, flowing into Switzerland as a location for research.

Overall, it is clear that despite dynamic growth in the international environment, Switzerland has so far failed to exploit this positive development for its own benefit as a research location and translate it into a further increase in prosperity in the form of more effective and efficient healthcare. This means missed investments, less innovation and a gradual loss of Switzerland's leading role in an important global industry. Now is the time to act. If Switzerland wants to remain at the forefront of medical advances, it is vital that greater support and promotion be provided for clinical research. ph

Share of global clinical trials in Phases 1–4 by region[20], in %

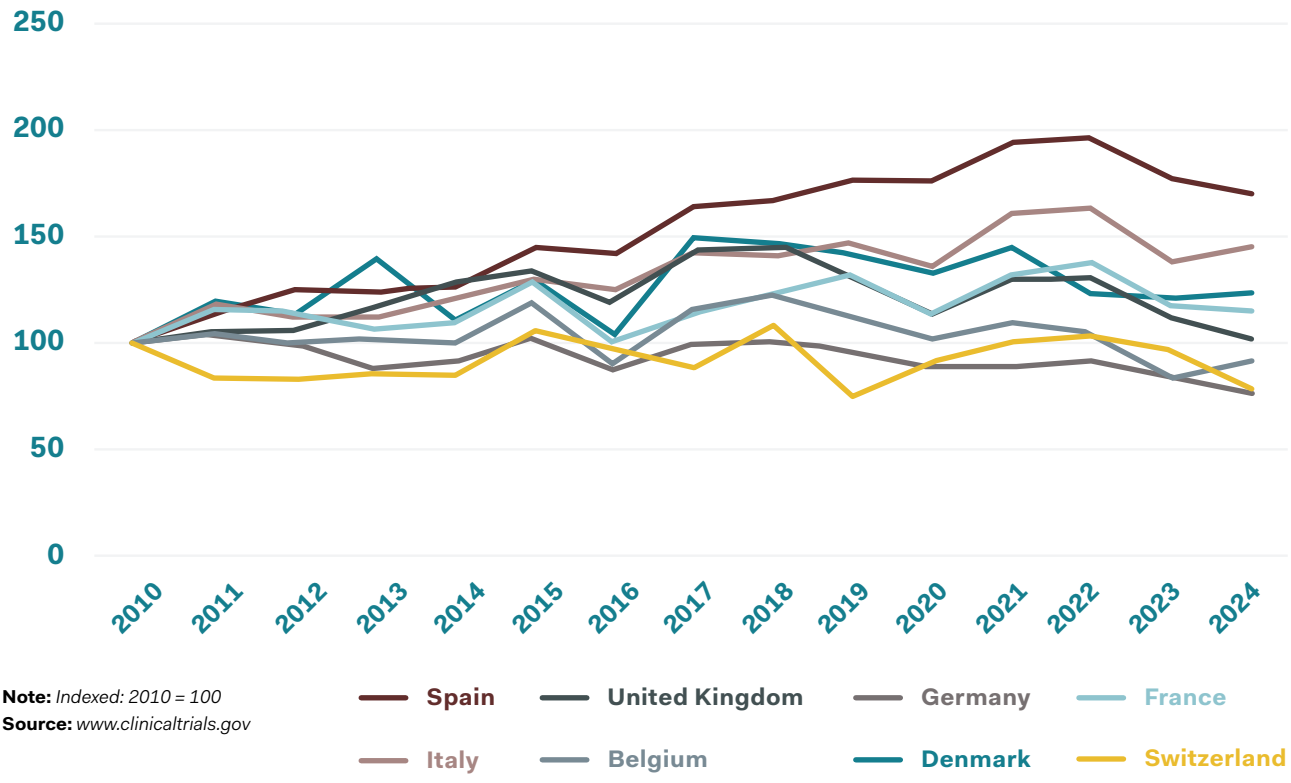
Figure 2-A



Source: *EFPIA, VE (2024): Assessing the clinical trial ecosystem in Europe.*

Change in the number of clinical trials in Phases 1–3 in Switzerland compared to selected European countries[19]

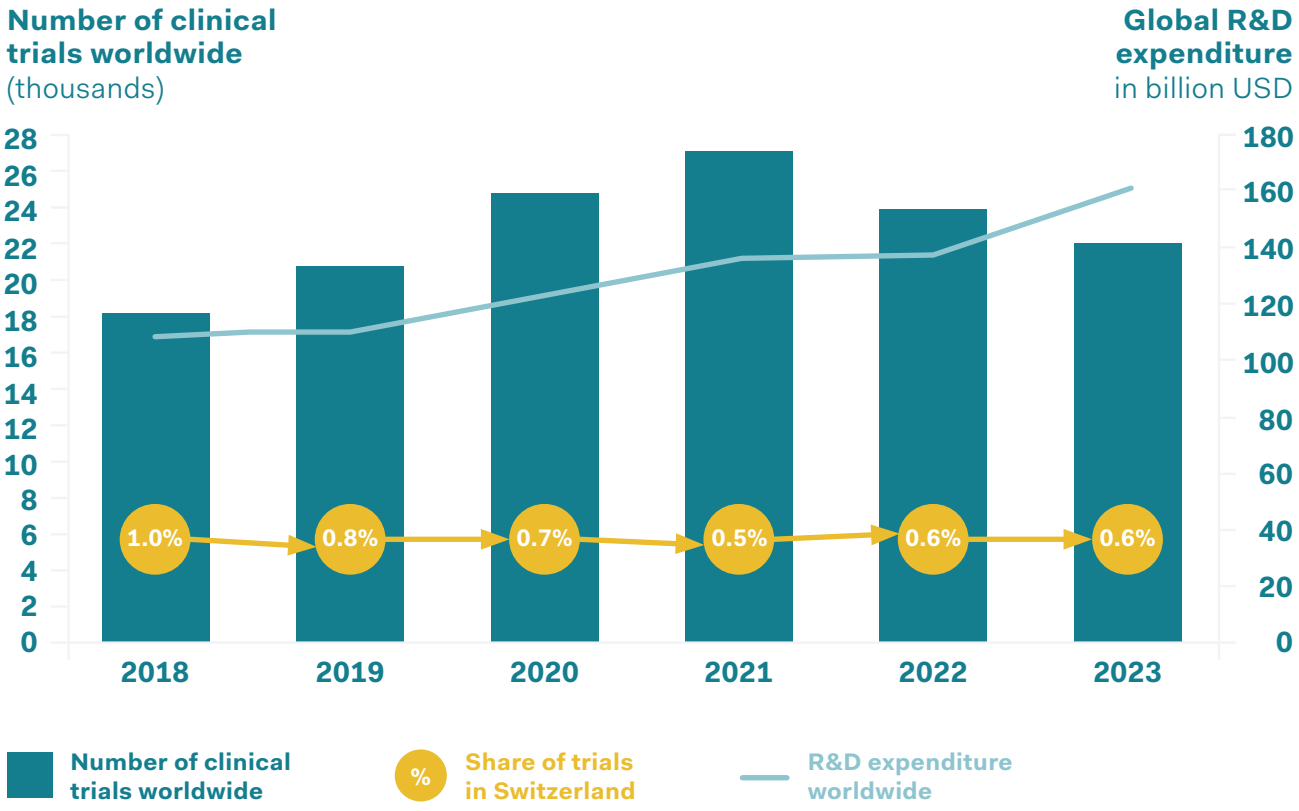
Figure 2-B



Note: *Indexed: 2010 = 100*
Source: *www.clinicaltrials.gov*

International comparison of clinical trials and global R&D expenditure 2018–2023

Figure 3



Sources: *Swissmedic, EFPIA, VE (2024): Assessing the clinical trial ecosystem in Europe.*

4

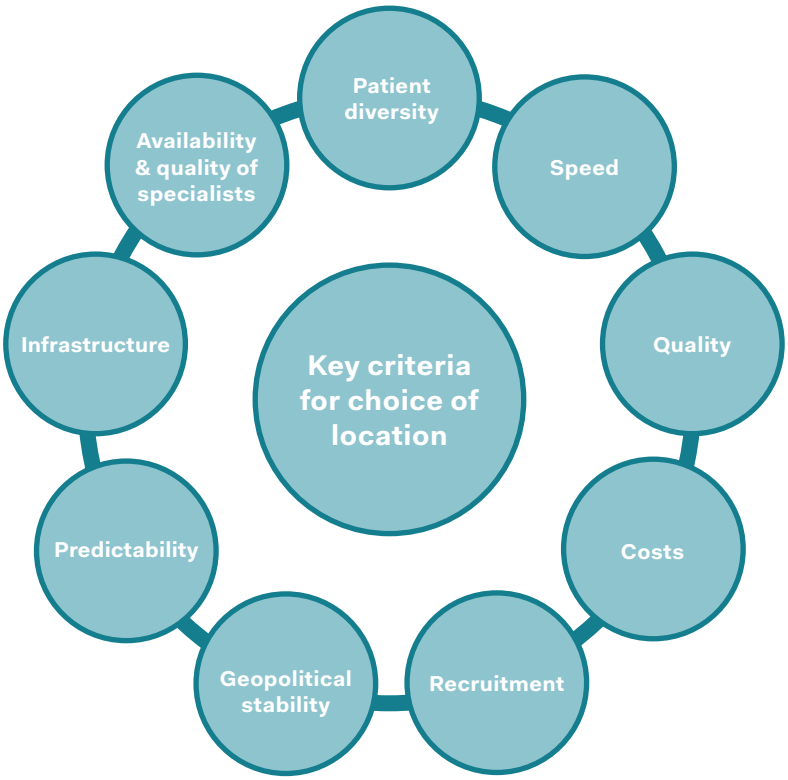
Various factors affect research companies' choice of location

Nowadays, most clinical trials are conducted internationally. The steadily growing challenges for clinical trials detailed above underline the importance of a carefully thought-out choice of location. There are factors that are difficult to influence, such as the size and diversity of a country's patient population. However, the clients of clinical trials – that is, study sponsors – take account of the entire process chain, from the planning, approval and implementation of clinical trials to the authorization and reimbursement of drugs following their completion. Each step of the process involves specific regulatory, scientific and organizational considerations, which play an important role in the choice of location (Figure 4). Many study sponsors operate globally and choose the countries around the world that best meet their requirements. Predictability and an efficient process have a decisive impact on a study's success and are key factors in the choice of location. Delays can not only significantly increase costs but also affect the results of clinical research and its usability. Accordingly, critical factors in the choice of location include, above all, the efficiency of the system, the quality and availability of infrastructure and specialist personnel, and the integration of clinical trials into the healthcare system. Demographic factors also play a significant role. For example, since the last partial revision of the legislation implementing the Human Research Act (HRA), researchers have been obliged to ensure that the groups of people being researched are relevant to the research question, particularly with regard to age and gender.

Switzerland must take all of these factors into account in order to strengthen its position as a preferred location for clinical trials. Although it is not possible to influence all factors directly, there is room for optimization in all process steps – and this task is incumbent upon all stakeholders in clinical trials. ph

Important criteria for the selection of clinical trial locations from the perspective of the global research-based pharmaceutical industry

Figure 4

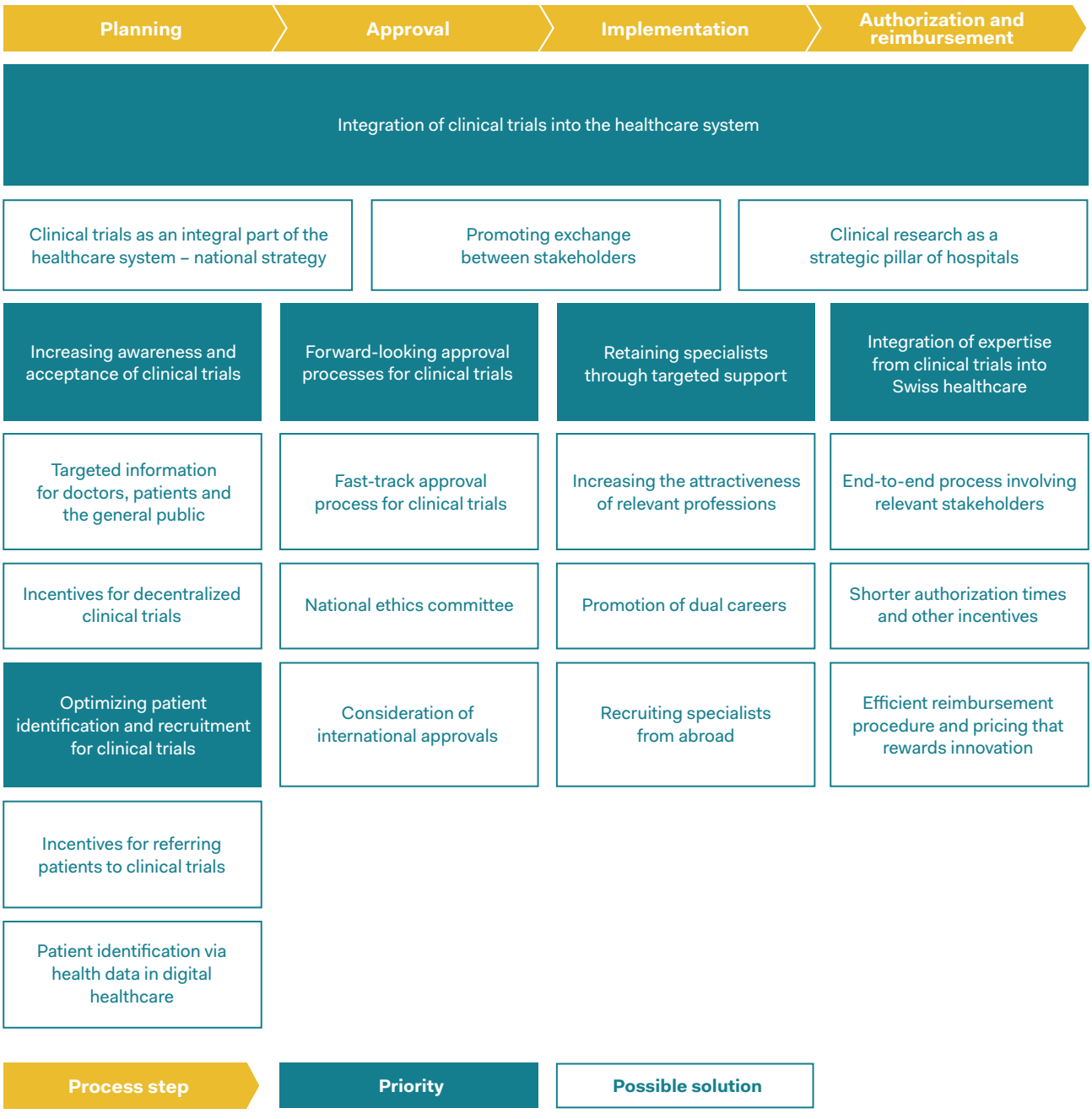


5

What priorities does Switzerland need to set in order to remain attractive as a location for clinical research?

Overview of priorities and solutions along the process chain for clinical trials

Figure 5



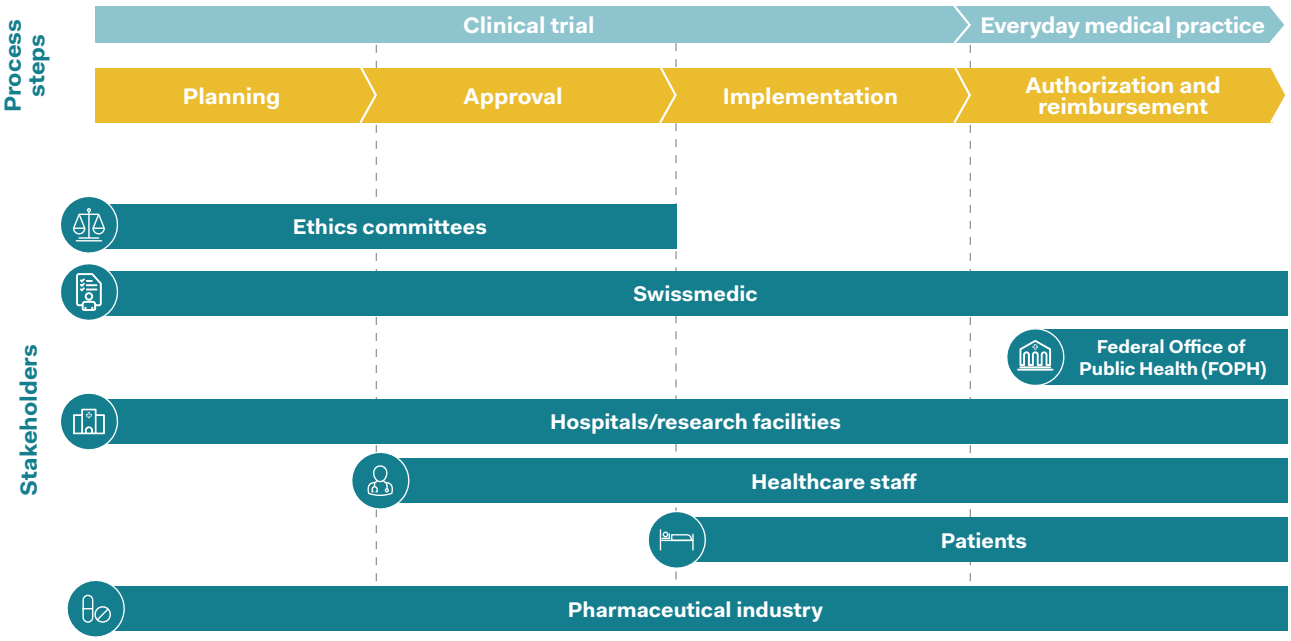
5.1

Overall process: the strategic importance of clinical trials in the healthcare system

The process of carrying out a clinical trial can be roughly broken down into three steps: (1) planning of clinical trials, (2) approval of clinical trials, and (3) implementation of clinical trials. When preparing for clinical trials, many study sponsors also take account of the next step, which is the (4) authorization and reimbursement of the drug following the trials' completion. In Switzerland, different stakeholders are involved in each step, and each step presents different challenges.

The clinical trial process, leading to potential authorization and reimbursement of a new drug

Figure 6



Priority: integration of clinical trials into the healthcare system

Today, the various stakeholders focus on their operational role in the process. Many are unaware of the crucial, overarching role they play in the location planning of international study sponsors, as they cannot adequately judge the overall picture. Clinical research in Switzerland takes place in what are known as study centers, a term that refers to the institutions whose medical staff carry out clinical trials. These institutions are primarily hospitals. Clinical trials are carried out in isolation from regular healthcare and are not sufficiently embedded in care structures or society. Public perception fails to fully appreciate the vital importance of clinical trials for Swiss patients and the Swiss healthcare system as a whole.

Possible solution: clinical trials as an integral part of the healthcare system – national strategy

Clinical research must be positioned as an integral, visible and relevant component of the Swiss healthcare system. A clear political vision for Switzerland as a research location would allow the research to be enshrined in this way. This approach would require not only a recognition of the importance of clinical research and a national strategy with clear objectives for Switzerland as a research location in the face of international competition, but also a national roadmap for how this could be achieved. In other countries, it is common to use the format of a "national pharmaceutical strategy" that sets out the vision and objectives for clinical research. Clarification of this kind provides guidance for all stakeholders and increases the visibility of clinical research in the public eye. Strategic measures are adopted in order to coordinate stakeholders and ensure targeted knowledge transfer of findings from clinical studies into healthcare – from study planning to authorization, reimbursement and beyond. The national objectives should be supported by earmarked funding that is secured on a long-term basis.

Possible solution: promoting exchange between stakeholders

Structured exchange between academic research, industry, study centers, patient organizations and public authorities is crucial for the targeted further development of clinical research in Switzerland. For example, regular roundtables could be held with all stakeholders in order to identify structural barriers and promote mutual understanding. This would speed up innovation processes and create new opportunities and framework conditions for clinical research in Switzerland.

Possible solution: clinical research as a strategic pillar of hospitals

Hospitals should understand and enshrine clinical research as an integral part of their mission. This requires clear strategic objectives, visible governance structures and targeted investments. Clinical trials must be recognized as a mark of quality and a driver of innovation in hospital operations. The greater priority afforded to clinical research in hospitals guarantees long-term financing of the necessary infrastructure and staff for high-quality clinical trials. It also promotes young scientists and a research-friendly hospital culture. Above all, this requires corresponding orientation and decision-making in health policy on the part of the cantons. ph

Life Sciences Sector Plan, UK

To counteract fragmented and slow drug development in an outdated system, the United Kingdom (UK) has developed a sector plan with a view to becoming the leading location for life sciences in Europe. This plan includes measures to promote research and development, attract investment, expand advanced manufacturing and accelerate innovation in the healthcare sector. Specific measures include an AI-supported health data platform, shorter processing times for clinical trials and more efficient regulatory processes.[21]

National pharmaceutical strategy, Germany

Germany is also experiencing a negative trend in terms of clinical trials initiated by pharmaceutical companies and has seen a reduction in its relative competitiveness as a research location. In response, the Federal Ministry of Health adopted a strategy paper in December 2023 setting out specific measures to improve the framework conditions for the pharmaceutical industry in Germany. These measures include, for example, shorter processing times for clinical trials, creating synergies among the authorities responsible for authorization, and advancing digital transformation in healthcare. Such measures form the basis for establishing financial priorities.[22]

5.2

Planning of clinical trials: creating operational conditions for implementation

The planning of a clinical trial is a key factor in its success. The study sponsor decides whether a location is suitable for carrying out the trial. This includes developing an understanding of relevant patients and treatment pathways and identifying researchers and study centers with expertise in the relevant therapeutic area. It is also necessary to draw up contracts with study centers, train study staff and establish data management systems.[23, 24, 25, 26] Careful planning lays the foundation for methodologically sound implementation and a smooth approval process.

Priority: increasing awareness and acceptance of clinical trials

The Swiss public has only a passing awareness of clinical research. Insufficient information and little knowledge of ongoing or planned clinical trials mean that patients are unable to benefit from innovative treatments at an early stage or that clinical trials are not conducted in Switzerland in the first place. For some patients, participation in a clinical trial may be the only way to access an innovative therapy. This lack of transparency hampers early planning and reduces trust in clinical research. Many patients perceive clinical trials as opaque or potentially risky, and there are hardly any incentives for doctors – apart from their own ethical and scientific motivation – to inform themselves and their patients about clinical trials and refer them for treatment. In order for Switzerland to continue playing a leading role in international clinical research in the future, action must be taken now to specifically improve the underlying conditions. Broad communication and clear information are needed to enable medical staff and patients to actively inform themselves about clinical trials and to motivate them to take part. It is vital that medical staff be encouraged to include clinical trials in treatment pathways as standard. For patients, participation in clinical trials can also become an additional burden. Many clinical trials require regular face-to-face consultations with the attending medical professionals – including for evaluation, treatment, examinations or follow-up appointments. Even if patients are fundamentally interested in the study, their willingness to participate can be hampered by long travel distances, limited mobility (possibly due to the disease in need of treatment) and significant time requirements.

Possible solution: targeted information for doctors, patients and the general public

Strategic provision of information to the general public is intended to promote both patient interest and the participation of doctors in clinical trials. The importance, safety and benefits of clinical trials are clearly communicated. The discussion of scientific benefits and achievements is intended to create trust and break down barriers in order to increase the recruitment rate and promote a more proactive culture of participation in clinical trials. HumRes, the FOPH's information platform for human research in Switzerland, is a user-friendly digital platform that provides an overview of ongoing and planned clinical trials. The platform offers easy access to trial information, supports targeted searches for suitable trials and allows direct registration. However, very few people are aware of the platform's existence. Extensive advertising of the new platform may help to raise awareness of clinical trials and their importance for Swiss patients.

Possible solution: incentives for decentralized clinical trials

Decentralized clinical trial formats facilitate participation by people from regions with poor infrastructure, people with reduced mobility, and people with significant professional and family commitments, (sometimes) allowing them to be treated and cared for at home and reducing the need for time-consuming consultations. There is a lack of a clear vision for how study centers can be supported in utilizing these decentralized elements. Electronic consent, follow-up treatment in your own home by a health professional, or follow-up medical consultations with the attending physician by video call, are clear examples of how decentralized clinical trials can deliver added value for patients. Here, there is a need for increased dialog and openness on the part of study centers and researchers in order to understand the challenges and tackle them in a targeted manner on the one hand, and so that they can explain decentralized clinical trial designs on the other. The position paper on decentralized clinical trials published by Swissmedic and swissethics in early 2025 is a move in the right direction. This paper recognizes the importance of the subject matter and urges in-depth dialog between stakeholders in order to drive forward the design of how decentralized trial elements are handled in the future.[37]

Public information on trials

Three information campaigns in the United Kingdom aim to increase people's willingness to participate in clinical trials. The "Be Part of Research" platform provides the public with information on over 6,000 active clinical trials and allows direct registration.[28] "Research for the Future" connects patients on an indication-specific basis and has over 19,000 registered volunteers and over 350 supported research projects.[29] "Join Dementia Research" matches people living with dementia to specific studies and has over 89,000 registered volunteers and 324 participating research centers.[30] These initiatives increase visibility, trust and willingness to participate among the population.

Promotion of decentralized clinical trials

Denmark has established an ecosystem for decentralized clinical trials that is supported by regulatory and digital infrastructure. A national framework led by the Medicines Agency and the public-private "Trial Nation" partnership defines clear standards and promotes telemedicine, eConsent and mobile study nurses. Coordinated processes and a digital healthcare system make participation easier for patients, regardless of location. This improves representativeness, reduces barriers to access and increases the efficiency of clinical research across the country.[31]

Priority: optimizing patient identification and recruitment for clinical trials

In order to carry out a trial successfully, it is important to understand whether there are enough patients in the country who could potentially be participants. One key obstacle is the patchwork of available data relating to diseases, patients and treatments. Existing data sources and networks are often fragmented, uncoordinated or hard to access. It is difficult to determine realistic numbers of trial participants and assess the suitability of Switzerland as a trial location. This leads to a greater risk of delays and inefficient allocation of resources at an early stage of planning. At the same time, the demands placed on the representativeness and diversity of trial populations have increased in recent years – in terms of age, gender, pre-existing conditions or origin, for example. To counter this, there is a need for new ways of identifying relevant target populations at an early stage.

Possible solution: patient identification via health data in digital healthcare

A digital healthcare system is the basic prerequisite for a national health data ecosystem, which is a key element in efficient trial planning, and offers a central overview and evaluations of disease and patient numbers. Launched in 2022, the DigiSanté program aims to transform the digital healthcare system in Switzerland by 2034 and enable standardized data collection and seamless collaboration between systems.[32] This should not only improve the quality of the healthcare system but also benefit clinical research. In the planning of clinical trials, suitable patients can be efficiently identified using a national data ecosystem in order to enable them to participate in a clinical trial. Until a central overview is available, queries regarding the number of patients are to be carried out using existing registry data to make it easier to identify suitable trial participants. Indication-specific matching can be ensured through collaborations with specialist associations. Anonymized and aggregated queries of structured data help to efficiently identify patients, plan clinical trials better, and bolster Switzerland's position as a location for clinical research.

Possible solution: incentives for referral of patients to clinical trials

If a clinical trial starts in Switzerland, there will be a certain number of study centers (e.g. hospitals) participating

National trial register

The Danish Civil Register enables lifelong recording of the health data of all citizens and links all personal data, including disease-specific registers and biobanks. Clinical trials are centrally coordinated across biobanks and research systems, medically suitable candidates are digitally assigned to them, and their participation is facilitated. The system increases transparency, allows matching by indication and strengthens trust in clinical research.[33]

in the trial. However, suitable patients should also be identified at other hospitals or medical centers and referred to a participating study center. It is only through the systematic involvement of attending physicians that all potential patients are given the opportunity to take part in clinical trials. Generally applicable incentive mechanisms should be created to ensure that attending physicians inform themselves about planned clinical trials and refer their patients to them. Possible incentives include the recognition of clinical research as part of medical training (further training points), regular feedback on the trial progress of referred patients, and recognition of their commitment to research. The referral process should be low-threshold (e.g. by means of digital solutions), and the flow of information must be guaranteed. This is the only way to ensure that all potential patients have the opportunity to participate in a clinical trial. ph

Centralized health data infrastructure

The United Kingdom has an interoperable national data infrastructure linking clinical, genomic and healthcare data. This allows trial administrators to access real-world data in anonymized form in order to optimize trial planning and location selection. The system improves patient identification, avoids redundancies, improves the quality of clinical research and speeds up the translation of research into care.

5.3

Approval of clinical trials: creating efficient regulatory conditions

Before they can be carried out, clinical trials require approval by the relevant authorities. In Switzerland, research projects requiring approval must be submitted to the relevant cantonal ethics committee and to Swissmedic. In particular, these reviews examine patient safety, scientific quality and ethical acceptability. There are seven cantonal ethics committees organized under the umbrella association Swissethics, which has been mandated by the FOPH to coordinate and harmonize procedures but has no authority to issue instructions to the ethics committees. The responsibilities and composition of the ethics committees are governed by the Human Research Act. In parallel to the relevant ethics committees, Swissmedic must review and approve applications for carrying out clinical trials. Swissmedic is the national pharmaceutical authority and an institution under public law affiliated to the Federal Department of Home Affairs. Swissmedic's duties are governed by the Therapeutic Products Act (TPA) and the associated ordinances.[35, 36]

Priority: forward-looking approval processes for clinical trials

The approval of clinical trials in Switzerland is a fast and high-quality procedure, particularly for clinical trials involving simple therapies and trial designs. In the case of new and complex trials, however, Switzerland could set itself apart from other countries by adopting even more efficient processes and reaching timely, comprehensible decisions while maintaining the highest quality standards.

Differences in the requirements and processes of the ethics committees lead to a patchwork of approaches, making it particularly difficult to carry out international clinical trials. A national ethics committee could achieve efficient and uniform reviews and remove bureaucratic hurdles, particularly in order to enable the well-founded evaluation of complex, highly specialized trial applications. Greater coordination between Swissmedic and the ethics committee would also be beneficial, as would established and collaborative procedures that help to avoid duplication and inefficient processes. An efficient approval process would boost trust and planning security and position Switzerland as an innovative location for clinical trials.

Possible solution: fast-track approval procedure for clinical trials

A legally enshrined fast-track procedure for the approval of clinical trials should be introduced in order to speed up the evaluation of urgent and innovative clinical trials. Preference could be given to clinical trials intended to test drugs for serious illnesses and those intended to address unmet medical needs – while maintaining the highest quality standards. The procedure would be underpinned by shorter deadlines and clearly defined time windows for decisions by the ethics committees and Swissmedic. This could speed up access to important new drugs through clinical trials – and speed up the treatment of patients for whom there is currently no therapy available.

Possible solution: national ethics committee

In view of the increasing complexity of clinical trials and the current lack of harmonization in the reviewing of trials by the seven cantonal ethics committees (guidelines, standards, benchmarks, etc.), a uniform assessment practice should be established for clinical trials of the same kind. A national ethics committee can ensure uniform and efficient review of clinical trials. This will lead to simplified approval procedures and improved quality of approval decisions, as well as reducing bureaucratic hurdles. In particular, a uniform system must be established for handling novel or complex clinical trial designs, for example, and experts can be efficiently brought in to strengthen the location for clinical research as a whole.

Possible solution: consideration of international approvals

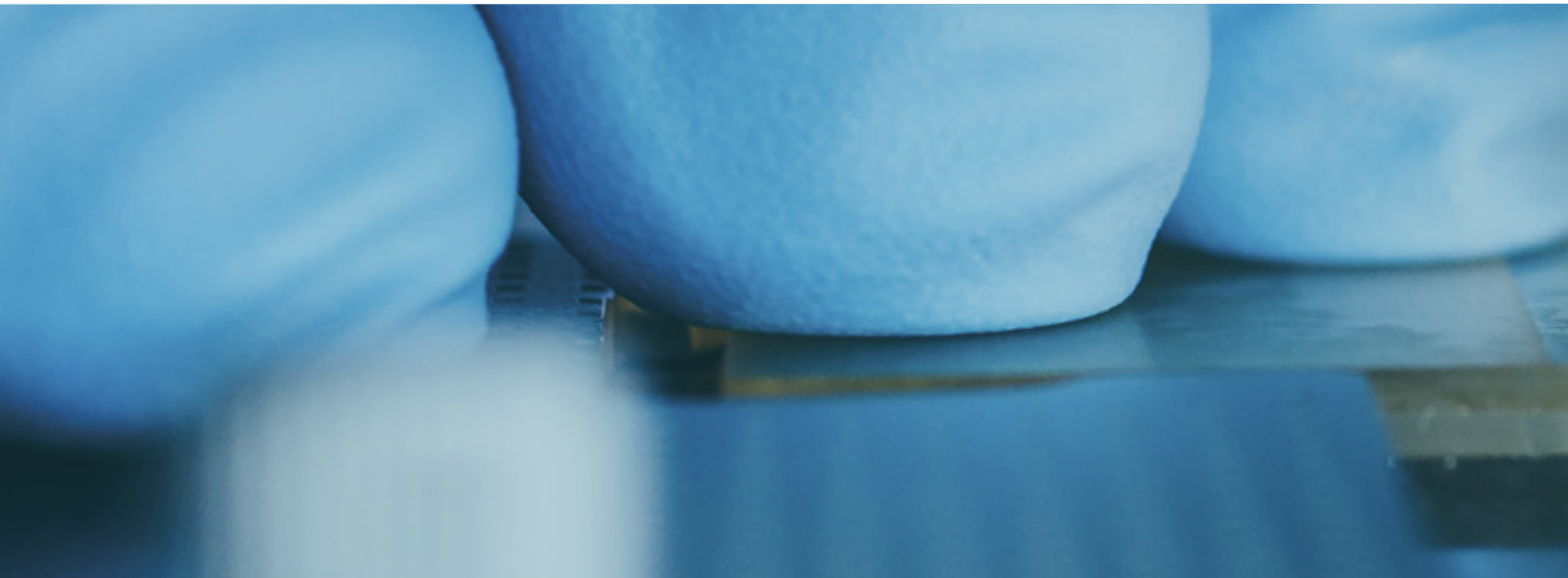
Existing data and assessments from other pharmaceutical authorities – such as the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA) – can already be taken into account in the Swiss approval process. Applicants can submit relevant documentation and refer to existing decisions. These documents and previously evaluated studies are supposed to increase transparency and knowledge transfer and avoid duplication in the process – without limiting national "evaluation sovereignty". This creates trust, strengthens Switzerland's position as a research location and promotes the risk- and evidence-based evaluation of internationally proven approaches. The international compatibility of key processes, structured exchange between national authorities, and transparent procedures that take international study protocols into account represent significant opportunities for Switzerland as a research location. ph

Standard patient form

In France, a standard consent form is required by law for all trials. This form is submitted centrally to the pharmaceutical authority and the ethics committees and is valid for all locations nationwide. It contains standardized information on the purpose, risks and patient rights and makes the process of reviewing trials for approval considerably easier. Researchers benefit from clear guidelines and legal certainty.[37]

Fast-track approval process

The UK's Health Research Authority offers a fast-track approval process in collaboration with the Research Ethics Committees. Originally developed for COVID-19 research, the authority has been expanded to include further clinical trials. The average approval period has been shortened by up to 50 %. Thanks to digital submission of applications, clear deadlines and targeted selection of approved ethics committees, clinical trials can be launched much more quickly. This model is used in particular for urgent, public and international clinical trials.[38]



5.4

Implementation: scientifically controlled implementation of clinical trials

Clinical trials are typically conducted in study centers under controlled conditions. Healthcare professionals lead the trial and play key roles in the proper application of therapies, monitoring, data collection and quality assurance. The efficacy and possible side effects of new therapies are investigated, and the results provide the scientific basis for the subsequent authorization of new drugs.

Priority: retaining specialists through targeted support

In order to carry out clinical trials, there is a need for sufficiently qualified specialists – in particular study nurses and study coordinators, who are responsible for the operational implementation of clinical trials. Swiss healthcare staff are excellently trained and implement trials to a very high standard. However, the available human resources at the study centers – especially in hospitals – are often overburdened, leading to delays in the coordination of appointments, data documentation and support for trial participants. In some cases, clinical trials cannot be carried out at all due to shortages of staff. For doctors and nursing staff, there is a lack of protected research time. In Switzerland, doctors carrying out clinical research usually do so in addition to their work as attending physicians, often without full compensation for the time spent. Study centers do not always recognize research activities.

Possible solution: increasing the attractiveness of relevant professions

Improving the quality and competitiveness of clinical trials in Switzerland in the long term calls for targeted investment in order to make better use of domestic skilled labor potential. There is a need for targeted programs for the expansion and career development of specialized professional profiles such as study coordinators or study nurses. These profiles should also include medical aspects so that, in addition to coordinating clinical trials, the specialists also work with patients, for example in the context of sampling work. Clearly defined job profiles, attractive working conditions and targeted promotion of young talent form the basis of a robust trial environment with a high level of expertise. Upgrading the profession in this way will increase its attractiveness and create new career prospects. Individual specialization and close ties to research institutions can reduce staff turnover at study centers, raising the quality of these centers and creating long-term stability in the implementation of clinical trials.

Possible solution: promotion of dual careers

There is a need for support schemes for dual careers in order to balance clinical activity (i.e. routine patient treatment) and scientific careers (i.e. active participation in clinical trials). Programs ideally start early in specialist training and offer protected research components that are linked to rotational positions or fixed modules. For example, dedicated percentages of working time reserved for research work could increase the attractiveness of clinical trial activities. Moreover, implementation should be supported by mentoring formats and central coordination offices. This structure bolsters the next generation of young scientists and improves the translational relevance of clinical trials.

Possible solution: recruiting specialists from abroad

With a view to closing existing gaps in clinical staffing, it is vital to ensure the recruitment of specialists from abroad as well as making maximum use of domestic skilled workers. Switzerland's flexible labor market is a strong point, but there are restrictions on access by specialists and highly skilled workers from abroad.

Structured university course on study management

The Medical University of Vienna offers a structured, part-time study program in the field of study management. This three-tier curriculum leads to recognized qualifications and trains students specifically for the role of study coordinator. The training provided combines theoretical knowledge with practical experience and creates clear career pathways, significantly increasing the attractiveness and professionalism of the occupational profile.[40]

The Agreement on the Free Movement of Persons with the EU makes it easier to recruit highly qualified workers from the EU – in particular, the Agreement allows cross-border commuters to work in Switzerland. As shown by the 2025 Europe Survey conducted by gfs.bern, 71% of respondents believe that Switzerland is dependent on skilled workers from the EU.[39] To combat the shortage of specialists in clinical research, it is important to ensure the continuation of these agreements. In addition, sufficient contingents from third countries must be made available in order to recruit suitable medical staff. We need adapted criteria that focus on the needs of the labor market – including in relation to international students who have already completed a relevant course of study in Switzerland. It should be possible to integrate these highly qualified specialists with links to the Swiss system into the Swiss labor market efficiently. ph

Dual career promotion in clinical work and research

In Germany, Clinician Scientist programs promote the compatibility of clinical work with research. The German Research Foundation (DFG) finances around 400 rotational positions that allow for protected research time during specialist training. Accompanied by mentoring, structures and financing, these programs bolster the next generation of young scientists, accelerate the implementation of scientific findings into everyday clinical practice and increase the relevance of clinical trials in healthcare provision.[41, 42]

5.5

Authorization and reimbursement: market launch of innovative new drugs

Once the clinical trial is completed, regardless of whether it was carried out in Switzerland, an application for authorization is submitted to the relevant authority – in Switzerland, to Swissmedic – so that the drug can be made available on the market. Authorization is based on a comprehensive dossier on the efficacy, safety and quality of the product. The price is then set by the Federal Office of Public Health.[43, 44] The process step of authorization and reimbursement marks the transition from clinical research into healthcare and determines whether patients in Switzerland will fundamentally have access to innovative treatments.

Priority: integration of expertise from clinical trials into Swiss healthcare

If the trial or parts thereof were conducted in Switzerland, there is a lack at this juncture of a link between clinical and existing regulatory experience on the one hand, and the processes of authorization and reimbursement on the other. Although results from trials at Swiss research sites are generally of a high standard, their potential in the regulatory and healthcare context is not yet systematically exploited. This leads to inefficiencies, duplication and potentially even to the loss of knowledge. Findings from clinical trials could be systematically integrated into the benefit assessments and pricing of new therapies. Expertise from clinical trials in Switzerland could serve as a driver for fast, evidence-based authorization and reimbursement processes and therefore speed up access to life-saving drugs. While other countries specifically build bridges between clinical research and healthcare, the use of trial results in the Swiss system remains largely ad hoc and project-based. Clear mechanisms are therefore needed in order to integrate existing expertise into authorization procedures, pricing and reimbursement decisions. Meanwhile, in other countries, specific incentives are provided in terms of authorization and reimbursement in order to encourage the local implementation of clinical trials. Incentives and authorization and reimbursement processes that are generally efficient act as a further driver to strengthen Switzerland's position as a location for clinical trials.

Possible solution: end-to-end process involving relevant stakeholders

A coordinated end-to-end process should link up interactions between participating authorities in the approval of clinical trials, marketing authorization and reimbursement. This would

already place the focus on a new drug's potential entry into the Swiss market during the approval of the clinical trial in Switzerland and ensure integrated procedures with binding submissions and coordinated communication between all stakeholders. One key element in this context is knowledge transfer. Currently, the experience of doctors who have carried out clinical trials is not included in the process as standard. However, specialists who supervise clinical trials should be able to systematically contribute their experience from trials to the corresponding authorization and reimbursement procedures. Healthcare professionals who have accompanied clinical trials have valuable experience and are particularly well qualified when it comes to making an objective assessment of the feasibility and benefit of specific therapies. Experience and expertise from Swissmedic and the ethics committee should also be taken into account when reviewing and approving clinical trials. With a view to optimizing the use of clinical research, the assessments and decisions of the ethics committees should be systematically reflected in the assessment of drug authorizations and in the pricing context if the underlying clinical trials were conducted in Switzerland. This bolsters the transfer of knowledge from clinical research into regulatory decisions and minimizes the duplication of assessment work.

Possible solution: shorter authorization times and other incentives

As in other countries, consideration should be given to shorter authorization periods, reduced authorization fees and extended document protection in the case of drugs where part of the clinical trials was conducted in Switzerland, among other countries. These incentives would help to boost Switzerland's importance as a location for clinical research, improve predictability and provide patients with faster access to innovative medicines

Possible solution: efficient reimbursement procedure and pricing that rewards innovation

The price-setting process in Switzerland is in need of thorough modernization. If drugs are made available to patients quickly by means of efficient reimbursement procedures, this will improve predictability and boost the country's attractiveness as a location for clinical trials. Conversely, recognition should be given for carrying out clinical trials in Switzerland. The pricing of medicines could include an incentive if the clinical trial of the drug was carried out in the country. This scheme would specifically promote investment in local trial activity, create locational advantages and bolster national participation in drug development. Companies would therefore be incentivized to carry out clinical trials in Switzerland. ph

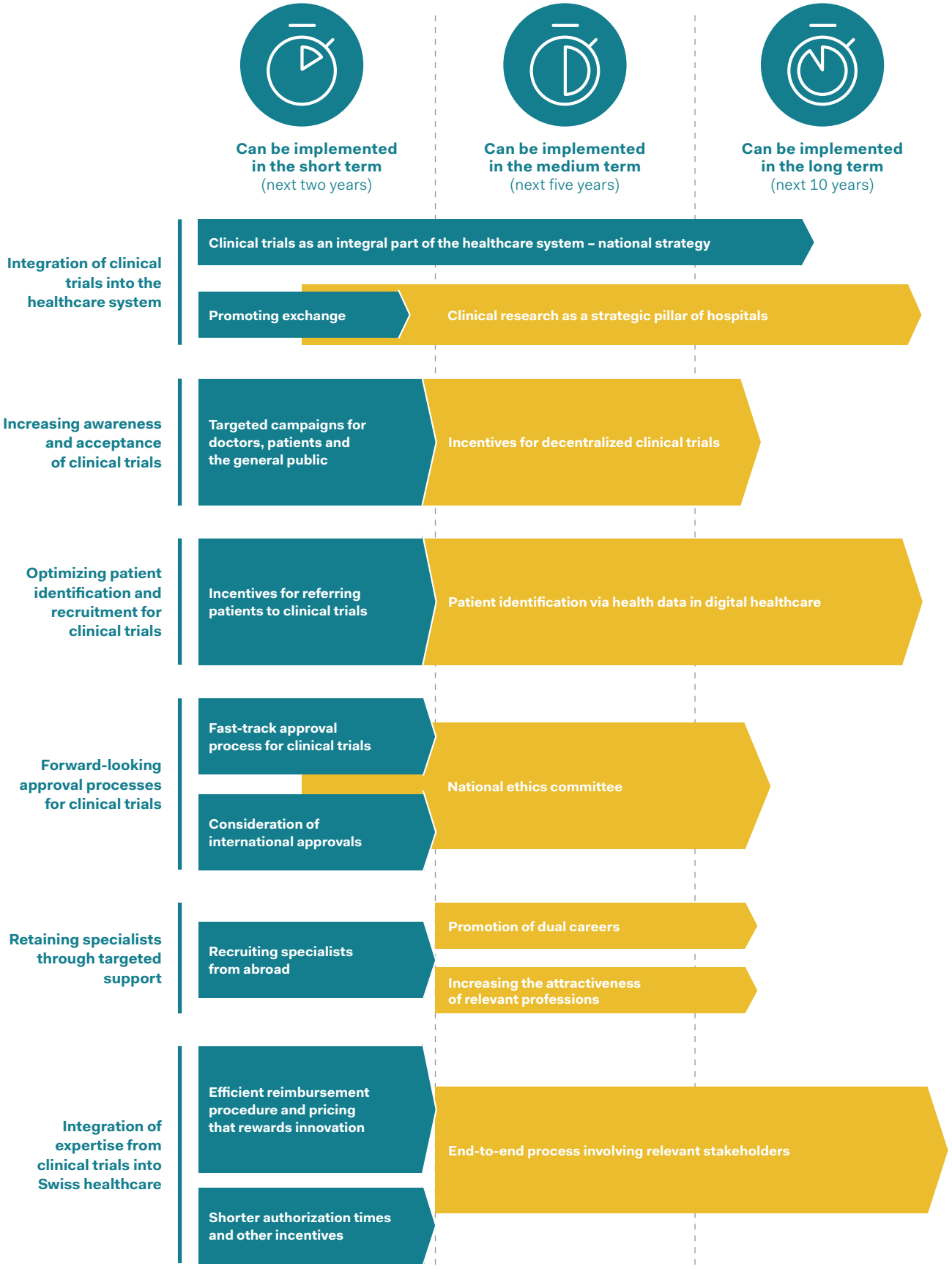
Faster processing of end-to-end authorization procedures

Since 2021, the British Innovative Licensing and Access Pathway (ILAP) has enabled shorter authorization processes for innovative medicines with strong medical potential. Using an Innovation Passport and a dynamic roadmap, the Medicines and Healthcare products Regulatory Agency (MHRA) coordinates the entire product cycle in collaboration with the Health Technology Assessment (HTA) authorities and the National Health Service (NHS). Early dialog, rolling review processes and uniform evaluations reduce time to market and improve patient access.[45, 46]

6

Roadmap for maintaining and strengthening Switzerland's position as a research location

Clinical research concerns all of us to some extent. Whether we are affected by serious illnesses or not, the positive effects of carrying out clinical trials in Switzerland are undeniable. Clinical research is also a key part of the Swiss healthcare system, which is internationally renowned for its high quality. The challenge now is to combine this quality with efficiency and attractiveness in order to bring more cutting-edge clinical research to Switzerland in the future. It is incumbent upon all stakeholders to implement measures aimed at ensuring the country remains a strong location for clinical research. In particular, policymakers (at the federal and cantonal level), authorities (ethics committees, Swissmedic, Federal Office of Public Health), hospitals, medical professionals, academic networks, patient organizations and the research-based pharmaceutical industry must act together to make this broad package of measures a reality and ensure that Switzerland is a future-proof location for clinical trials. ph


Can be implemented in the short term (next two years)
Can be implemented in the medium term (next five years)
Can be implemented in the long term (next 10 years)
Integration of clinical trials into the healthcare system
Clinical trials as an integral part of the healthcare system – national strategy
Promoting exchange
Clinical research as a strategic pillar of hospitals
Increasing awareness and acceptance of clinical trials
Targeted campaigns for doctors, patients and the general public
Incentives for decentralized clinical trials
Optimizing patient identification and recruitment for clinical trials
Incentives for referring patients to clinical trials
Patient identification via health data in digital healthcare
Forward-looking approval processes for clinical trials
Fast-track approval process for clinical trials
National ethics committee
Consideration of international approvals
Retaining specialists through targeted support
Recruiting specialists from abroad
Promotion of dual careers
Increasing the attractiveness of relevant professions
Integration of expertise from clinical trials into Swiss healthcare
Efficient reimbursement procedure and pricing that rewards innovation
End-to-end process involving relevant stakeholders
Shorter authorization times and other incentives

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About Interpharma

Interpharma, the association of Switzerland's research-based pharmaceutical industry, represents the country's strongest export sector. The market for pharmaceutical products sold abroad is valued around CHF 115 billion annually. In Switzerland, our member companies hold more than 90% of the market share of patented medicines and invest approximately CHF 9.2 billion in research and development in Switzerland.

Association of Switzerland's research-based pharmaceutical industry
Petersgraben 35, Postfach, 4009 Basel, Switzerland
Telephone: +41 (0)61 264 34 00
Email: info@interpharma.ch
Website: www.interpharma.ch