

Personalized healthcare in Switzerland – holistic assessment by experts

Sponsored by Roche Pharma (Switzerland) Ltd

Online Version



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Comment

All designations of professions/persons used in the masculine form in this document are intended to be neutral with regard to the sexes and refer to both women and men.

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“Personalized healthcare fundamentally changes patient care”

Personalized healthcare: here is a topic that brings out much hope, expectations and challenges for patients, doctors, the industry and the healthcare system in general. Consequently, I am so pleased, dear readers, to offer you in this brochure the current situation of the discussion on personalized healthcare in Switzerland.



Dr. Oliver Bleck
General Manager, Roche
Pharma (Switzerland) Ltd

In this document, experts present different aspects of the topic of personalized healthcare and they provide insight on different relevant angles. Overall, personalized healthcare is discussed as a trans-disciplinary approach and the future prospects, as well as the issues with regard to its benefit, its funding and the political aspects are discussed.

This brochure came to fruition following a forum during which various stakeholders participated and that was organised by Roche Pharma (Switzerland) Ltd in October 2019. Representatives from the medical community, patient organisations, the political sphere, health insurance, industry, education and research openly discussed the opportunities and challenges. The different per-

spectives all focused on common issues: How can we help and understand patients better with their individual needs? What is the role of personalized healthcare with regard to this? All were unanimously in agreement that the different stakeholders should work together more closely to reach this objective and therefore achieve a positive change in the healthcare system.

Finally, this brochure also discusses the increased use of new possibilities in the healthcare system, improved diagnostic methods (e.g., routine genetic testing for tumour tissue), as well as the use of artificial intelligence, machine learning and big data. These aspects are also consistent with the discussion about data protection and collection.

Research has made us progress together on the path of personalized healthcare. This path will lead to more efficient solutions for patients and will therefore profoundly change the entire healthcare system.

In order to allow patients in Switzerland to continue to have timely and sustainable access to innovative and modern treatments within the scope of personalized healthcare in the Swiss healthcare

system, we are committed to the Foreword development of the existing system in different areas:

1. Quicker authorisations of innovations and adaptations of Swissmedic authorisation conditions based on new scientific knowledge, with for example the consideration of evidence from real-world data (following the example of other regulatory authorities, such as for example the FDA), in order to better consider the properties of personalized treatments.
2. Additional reimbursement and price models, which allow for personalized treatment for patients based on scientifically supported therapeutic guidelines and issued by medical committees (e.g. tumour boards, companies in the medical field).
3. Implementation of a digital infrastructure for the collection, aggregation and analysis of health data in view of obtaining optimal benefits for patients.

No stakeholder is able to single-handedly implement all of these objectives and transform the healthcare system. At Roche, we work together closely with many other stakeholders from the healthcare sector in order to manage the potential of personalized healthcare better for the benefit of all patients.

As a dermatology specialist and General Manager of Roche Pharma (Switzerland) Ltd, my primary objective is, and has always been, to find the right treatment for the right patient at the right time in order to help patients live better and longer.

The success of implementing personalized healthcare is in our hands; let's do this together!



Dr. Oliver Bleck

General Manager Roche Pharma (Switzerland) Ltd

“Insight, perspective and outlook” – key takeaways from the event

In October 2019, Roche Pharma (Switzerland) Ltd organised the first Roche Forum “Personalized Healthcare” in Zurich in order to discuss the challenges and opportunities with representatives from patient organisations, the medical community, the political sphere, health insurance, academia and the industry.

Since the decoding of the human genome, medical knowledge has progressed at a rapid speed: it is estimated that in 2020, the amount of medical knowledge available on a global scale doubles every seventy-three days.¹ In particular, in cancer research, this increased knowledge is now already being put to good use: through the analysis of genetic databanks, it is possible to study and develop new treatments, which are tailored to the individual genetic characteristics of each patient and should also make it possible to obtain better therapeutic success. The abandonment of treatments for the masses in favour of personalized healthcare, which is tailored to the needs of each individual, nevertheless assumes a change in mentality of all stakeholders. Personalized healthcare is a multidisciplinary approach that requires the mobilisation of all stakeholders, whether this be for data collection and evaluation, for the authorisation and funding of treatments or for societal debates on health benefits.

The place of medicine in a digitised world

In his opening presentation, Stephan Sigrist of Think Tank W.I.R.E. provided an overview of the history of medicine, starting from the individualised analysis practised by ancient healers up to standardised medicine, which today forms the foundation of our healthcare system. Through computing power and increasing genetic knowledge, some treatments are now individualised again. The massive volumes of data that are associated with it still pose new challenges, such as for example the guarantee of data quality and data processing. Following the introduction there was a discussion facilitated by Beatrice Müller to assess the topic from different perspectives.

Perspective of a patient organisation

Brida von Castelberg (Swiss Patient Organisation

SPO Foundation) described her long-standing irritation that medicines are most often tested in young men, whereas the knowledge resulting from medicines must be applied to the entire population. It has already bothered her for a long time that she has to prescribe the same preparations to a strong boxer and a slender Asian woman. With this in mind, we should be congratulating ourselves on personalized healthcare; in particular for oncology treatments, the probability of success has significantly increased through the determination of molecular tumour profiles. Ms von Castelberg made an eloquent comparison: similar to fashion, there is in medicine ready-to-wear manufacturing, which is cheap and which will be more or less suitable for the majority of people. As for personalized healthcare, it corresponds to high fashion, with the corresponding prices.

“This has always bothered me: A small Asian woman and a boxer receive the same medicines!”

– Brida von Castelberg

What do we do with the knowledge available?

“The health of an individual largely depends on his genetics, socioeconomic situation, education, diet and lifestyle,” according to the speaker. In the future, genetic testing will provide clues as to not only the presence of an acute disease but also risks of genetic origin. “But what will we do?” she asked the other participants. “Will we require these persons in the future to adopt a tailored lifestyle? With inevitable consequences?” Personalized healthcare therefore raises the issue of knowing at what point an individual becomes a patient. As soon as we know that he has a genetic risk? Here is her conclusion: The personalization of medicine should be welcomed globally but we must not overestimate its impact on health. A good relationship between patients and their doctors remains the main focus.

Perspective of the FMH (Swiss Medical Association)

Yvonne Gilli (FMH) has taken the floor from the previous speaker and cited Stephen K. Klasko,² who calls for a change in the professional profile of doctors: “It is much more necessary to focus on social science competences, humanist principles, cross-cultural knowledge and on relational skills.”

Consequently, she proposed discussing the idea of the human being and to aspire to a paradigm shift, while abandoning sector-specific thinking in favour of interdisciplinary, joined up thinking. While referring to the Meikirch model,² Yvonne Gilli suggested considering health in a more global

manner, taking into account the environment as a whole. This also involves reflecting on the manner in which we should manage the increasing flow of data.

“A discussion should be engaged about fundamental rights in the digital era: the right to know and not know, self-determination, frailty, the data of minors and the protection of data.”

– Yvonne Gilli

How do we give doctors the weapons required?

Doctors should be able to analyse data and accompany patients in this regard. She concluded that, for the FMH, training should be adapted to new challenges. With the massive quantity of data, we find ourselves today especially confronted with essential qualities that are not measurable with “simple” indicators, such as for example the evaluation of the quality of life. Personalized healthcare gives us the opportunity to understand the life conditions of each patient better, but this is only possible while relying on humanist principles. “A discussion should be engaged about fundamental rights in the digital era: the right to know and not know, self-determination, frailty, the data of minors, the protection of data.” What is the situation with equality in access tailored to need for medical services?”

Perspective of a health insurer

Matthias Schenker (CSS) has essentially referred to increasing medical progress and untimely influences in the system, which would be the cause of increasing healthcare costs. In addition, there would still be treatments that do not provide the expected benefit and would therefore be ineffective on the systemic level. In this regard, Mr Schen-

ker hopes for a potential improvement through personalized healthcare. However, he warned against an excessive use of personalization: it would not be acceptable that the costs of research for individualised treatments are ultimately assumed by the social security system.

“The financial risks should be distributed better on the shoulders of premium payers and the industry.”

– Matthias Schenker

How should personalized healthcare be funded?

In personalized healthcare also, it is essential that patients access the healthcare system at the right time and at the right location and benefit from a medicinal product that is the subject of a horizontal and vertical integration. It is only through this global approach that personalized healthcare would be tolerable for society. “If personalized healthcare aspires to completely individualised care, it will not be fundable”; this was Matthias Schenker’s first conclusion. Personalized healthcare would also end in failure if the FOPH opposed new forms of reimbursement and if the insurers would only be interested in the optimisation of costs and in the maximisation of profits and would ask of patients to receive healthcare that is not optimal but with a maximum limit.

“If the patient experiences the success of personalized healthcare on both the levels of health and his wallet, then he will also be ready to provide his digital data for this purpose. With patience and determination, we will reach an equilibrium”; this is the speaker’s conviction. In order for the risks to be distributed better on the shoulders of premium payers and the industry, it is necessary that the evaluation parameters are measured systematically, that the findings are published and that the

reimbursement models are tailored on the basis of this knowledge.

Perspective of a politician

Ruth Humbel (Aargau National Councillor, CVP (Christlichdemokratische Volkspartei der Schweiz [Christian Democratic People’s Party of Switzerland])) emphasised that, for her, personalized healthcare assumes a global vision of human beings. Today, national politics covers many areas that are under construction in the healthcare sector, including, amongst others, TarMed, the regulating of prices for medicines, the uniform funding of outpatient and inpatient services, as well as the funding of care. This would explain why the forces required for global visions in the healthcare sector tend to lack on the federal scale. There are several federal strategies that overlap with personalized healthcare, such as for example the e-Health strategy and the national strategy against cancer, but there is, however, no national strategy focusing specifically on personalized healthcare. In addition, many aspects relating to health policy are governed on the cantonal scale, which complicates national coordination.

“In Switzerland, there is not only one minister of health but also cantonal health directors, which brings the number of decision-makers to twenty-seven. This complicates national coordination.”

– Ruth Humbel

What is the political focus?

Reforms are particularly required in the areas of funding and reimbursement models. “Switzerland is a rich country with complete basic insurance, but it delegates to insurers regarding the funding of healthcare services, specifically in the most delicate area, namely that of innovative treat-

ments. Access to all is complicated,” summarised the politician. Finally, in personalized healthcare, it is necessary to find a joint solution to the issue of knowing which treatments will be funded by the social security system. On this point, Ruth Humbel believes that it is the responsibility of the political system to take control and, for example, to advance the development of new reimbursement models. For this purpose, it would, however, be necessary to specifically define the benefit of personalized healthcare. In this context, greater transparency from the industry regarding the prices for medicines would also be necessary in order to build trust. Concerning digitisation, she emphasised that data protection was certainly very important, but it could also slow down progress.

Perspective of Roche Pharma (Switzerland) Ltd

For Jean-Marc Häusler, Medical Director of Roche Pharma (Switzerland) Ltd, personalized healthcare represents an ambitious objective and it still remains a vision for the future. Its strengths reside in increased therapeutic efficacy, in the avoidance of unnecessary treatments, but also in acquiring a much deeper understanding of diseases. It ultimately leads to a better allocation of resources in the healthcare system.

However, this future is coming faster than many believe and therefore now is the time to take the appropriate measures to contribute to its arrival, indicated Jean-Marc Häusler. “We see such an abundance of data that it is now possible to liaise with the personal needs of individuals. For the industry, this is a passage into a new era, a paradigm shift and quite simply the future of medicine.” The Roche company has therefore organised itself accordingly and it already unites state-of-the-art diagnostics and innovative medicines under one roof.

Jean-Marc Häusler discussed a third cornerstone of Roche’s strategy that until now has not been noticed very much: Roche also invests intensively in data analysis and corresponding tools. The integration of all three areas will advance medicine. “Switzerland is in a favourable position and has great strength for innovation, but we need to ask ourselves to what extent are we ready to rise to the challenge,” continued Jean-Marc Häusler.

“At Roche, we work intensively to develop new authorisation and reimbursement models in order to ensure access to personalized treatments for patients.”

– Jean-Marc Häusler

At what level is it necessary to act?

According to the speaker, developments are necessary in terms of the highly fragmented availability of electronic data. Ethical and legal issues still remain largely unanswered. Concerning the authorisation procedure, Jean-Marc Häusler indicated that, for personalized healthcare, it is no longer possible to work with large conventional studies, but it is necessary to turn to small communities and real-world data. This step has not yet been reached in the Swiss authorisation practice. “Limited-duration authorisation”, in which it is possible to send efficacy data at a later date, could constitute an initial step to remedy it.

Reimbursement also still depends too heavily on conventional approval studies. Roche Pharma (Switzerland) Ltd is open to new pricing models, while using, for example, anticipatory services. There would only be reimbursement after attaining a previously defined benefit. Therapeutic outcomes are therefore at the forefront. For this purpose, a joint action with all stakeholders from the healthcare sector is essential.

Perspective of the SPHN

“I am the most impatient among the persons present”; it is with this comment that Peter Meier-Abt from the Swiss Personalized Healthcare Network (SPHN) began his presentation. For more than twenty years, he has been dedicated to personalized healthcare, including concepts that for a long time have already been applied in everyday medical practice. For example, in clinical pharmacy, where this involves proposing the right medicine, at the right time, at the correct dose, to the right patient. In contrast, the required infrastructure is still lacking.

“Switzerland is significantly behind compared to other European countries: for example, in the Netherlands, for many years information about genetic mutations causing altered pharmacokinetics in some medicines has been saved on chip cards that the people concerned bring with them.” In Switzerland, such systematic sharing is lacking. Research in Switzerland also suffers as a result of systematised data not being available on a national scale. We have needed IT systems to collect and share biomedical data for all of Switzerland for a long time.

“We need a data structure on a national scale – we must achieve it!”

– Peter Meier-Abt

What about a national healthcare system as a solution for the future?

In order to make personalized healthcare a reality, Switzerland should orientate itself towards a national healthcare system. “Otherwise, it’s impossible,” Peter Meier-Abt emphasised. Currently, patient data cannot be transferred simply from one canton to another. “Switzerland only can allow for such unnecessary obstacles, because the pressure for savings is too low.”

A national data pool would be essential, not only for research but also for the quality of healthcare in Switzerland. The SPHN was developed from 2012 with the State Secretariat for Education, Research and Innovation (SERI) and it has been operational since 2017. Up to 2020, the priority has been to support the university hospitals, then the cantonal hospitals and the smaller hospitals will be associated, as well as surgeries later.

In addition, the connection with a patient’s electronic record is on hold. In this regard, Peter Meier-Abt reported significant gaps in the collaboration between the SERI and the FOPH: of course, the concerns about data protection and sovereignty should be taken seriously and taken into account, but this would be feasible if there was a willingness in accordance with this. If we look at the changes abroad, we see that Switzerland must urgently catch up.

Round table

After the keynote presentations of the different participants, major topics were discussed at a common round table. Discussions were in particular dominated by ethical implications, data protection, funding issues and the concrete possibilities for cooperation.

Personalized healthcare should be focused on humans, not on an algorithm

Participants in the round table unanimously agreed on the fact that humans should be central, despite the increasing use of new technologies in personalized healthcare. In addition, it is essential that society be fully informed on all aspects of personalized healthcare. This is an interprofessional mission of all stakeholders from the healthcare system. Unlocking data should be carefully discussed with patients, which helps in many cases to

obtain consent for their use, according to Peter Meier-Abt.

Access to treatment is central

The representatives of patients and doctors demanded the initiating of an ethical framework around the decision to give a patient access to a defined treatment. The patient’s immediate environment and the Ethics Committee should also be involved. As for the FMH, Yvonne Gilli has furthermore requested that insurers regulate, in an industry solution, how personalized healthcare will be reimbursed. This aspect could already be handled today, for example, with off-label use. There must in no case be an algorithm that decides who receives a treatment. In order for funding to remain guaranteed, it is ultimately necessary that all stakeholders make a contribution. And the definition of the benefit of personalized healthcare allows for the overall management of the system. Furthermore, it is not necessary that the pharmaceutical industry allocates resources exclusively to personalized healthcare, but it should continue to invest in research and development in every sense. Someone from the public asked if it would be ethically acceptable to provide the pharmaceutical industry with data collection funded by public officials so that it can be used to develop products that generate profits. Peter Meier-Abt answered that this perception is based on false assumptions: the patient’s consent is always required before his data can be used. The data are held by the service providers but they belong to the patients. And personalized healthcare and therefore tailored medicines ultimately benefit everyone, added Jean-Marc Häusler.

Personalized healthcare – a cultural change

Based on her experience as a politician, Ruth Humbel expressed the assumption according to

which the issue of data protection could in reality not have such a significant importance in the eyes of patients. However, the open questions about data governance, the confusing separation of power, the questionable independence of research regarding the industry and the schemes in the publishing of study data have led to the public’s ambivalent attitude towards personalized healthcare and the data sharing that it involves. At this level, a change in mindset is necessary, considered Peter Meier-Abt. Yvonne Gilli and Brida von Castelberg asked for there to be a public debate about what exactly is desirable and feasible. Today, it is not possible to predict if personalized healthcare would make the healthcare system more expensive or not. But in any case, we would gain more effective medicine.

“Data belongs to the patients.”

– Peter Meier-Abt

The speakers agreed that personalized healthcare represents an extremely rapid development, which constitutes an opportunity and to which all stakeholders must make an active contribution. Therefore, investing in personalized healthcare is a good thing in substance. At the same time, societal reflection in relation to certain open questions and challenges is necessary, for example, concerning data protection, the evaluation of the benefit and funding. For this, all stakeholders should conduct reflection beyond their own sector and establish reliable cooperation. Collaboration is the only way to also initiate trust.

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- ³ Additional information: www.meikirch-modell.ch

“Major trends in medicine – where are we going?”

Interview about perspectives with Prof. Olivier Michielin, Head Doctor at the Oncology Department and Head of Precision Oncology Center at the CHUV (Centre Hospitalier Universitaire Vaudois [Lausanne University Hospital]) and Prof. Serge Bignens, Director of the Institute for Medical Informatics I4MI at Bern University of Applied Sciences BFH (Berne Fachhochschule).



Prof. Olivier Michielin
Head Doctor at the
Oncology Department,
Head of Precision Oncology
Center, CHUV (Lausanne
University Hospital)



Prof. Serge Bignens
Director of the Institute
for Medical Informatics
I4MI at BFH (Bern Univer-
sity of Applied Sciences)

What “major trends” in personalized healthcare are currently emerging in research, clinical practice and informatics? What development factors do you discern?

Serge Bignens: “The major trends are genome sequencing, mobile sensors and data analysis and therefore topics such as artificial intelligence, machine learning, and big data. Our healthcare system will benefit in three ways: 1) in diagnosis and acute treatments, 2) in chronic treatments and

3) in prevention. In the first two points, these technologies are already used, particularly in the fight against cancer. An important driving force of personalized healthcare is also the increasing ageing population and therefore the associated chronic diseases and the need to find tailored solutions to respond to these. In the future, prevention will also be optimised with personal parameters, through the consideration of environmental factors using various sensors (24/7 recording via watches, bracelets, applications, etc.). New devices will make it possible to assess contextual factors with increasing accuracy, for example, an insulin pump with an integrated blood glucose measurement, a measuring device in the form of a tablet that only needs to be swallowed, rapid blood tests that could be done at home, earpieces that will record heart rate, blood pressure and ECG, etc. If we follow the current trends in the informatics industry, we see that these changes are being established.”

Olivier Michielin: “Oncology is one of the pioneers in personalized healthcare. Broad international data have already been helping us in patient care for many years. The next generation of genetic sequencing will allow for new strategies for personalized treatments. In the near future, we aim to register all our patients in a structured database common to all of Switzerland, which will make it possible to use predictive artificial intelligence.

This data will enrich the doctor’s advising role by providing information on the individual benefits of a specific treatment. Therefore, in the future, treatment decisions will also increasingly depend more often on data analyses. The field of artificial intelligence and statistics will play a more important role in the training of doctors and should already be part of the curriculum at an early stage. However, an empathetic relationship with the patient remains the foundation of a doctor’s duty.”

“The field of artificial intelligence and statistics will play a more important role in the training of doctors and should already be part of the curriculum an early stage.”

– Olivier Michielin

The collecting of “real-world data”

The data that are currently being collected to allow for accurate oncology methods are primarily standard molecular and clinical data. However, it is possible that the additional data provided, for example, via smartphone applications, can help extend the scope of our research. In this context, Serge Bignens insists on a current reality: to give an example, some weeks after a patient’s discharge from hospital, there is almost no information on disease progression and if he continues to take his medication regularly. Currently, only a few specific diagnoses are linked to registries. In Great Britain, however, the measurement of patient diabetic results is, for example, widespread and the surgeries keep their patients’ target blood glucose levels under control and receive a financial benefit. In Denmark, the national electronic medical record was equipped with an Opt-Out¹ and, under certain

conditions, these data may be used for research purposes. In contrast, Switzerland gives great importance to data protection and has no such measures to date.

What challenges and opportunities result from the implementation of these major trends in Switzerland?

Olivier Michielin: “In fact, the access to medicines regulated by Article 71a-d of the KVV (Krankenversicherungsverordnung [Health Insurance Ordinance]) is to be welcomed, because for patients with cancer it opens many possibilities. This article may be expanded to allow for, for example, the collecting of evidence on efficacy based on which medications would be authorised for new treatments. This would be a simple adjustment that would have a great impact.”

Serge Bignens: “It would actually be urgent to show what patients specifically receive from their consent to use their health data. Furthermore, the principle of social security for basic insurance applies for the costs for our health, whereas for data, we, the patients, we prefer to keep them for ourselves! Why?! Providing personal data for research would be an act of solidarity, which would make our healthcare available to all.”

“Providing personal data for research would be an act of solidarity, which would make our healthcare available to all.”

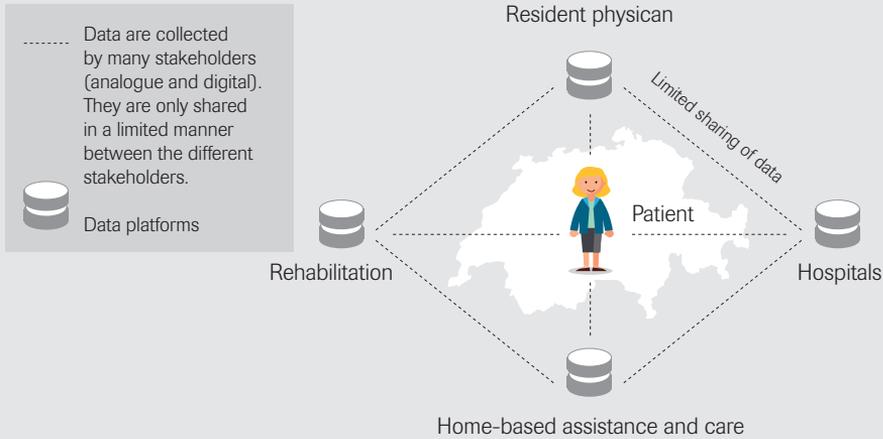
– Serge Bignens

Exciting years await medicine and our healthcare system.

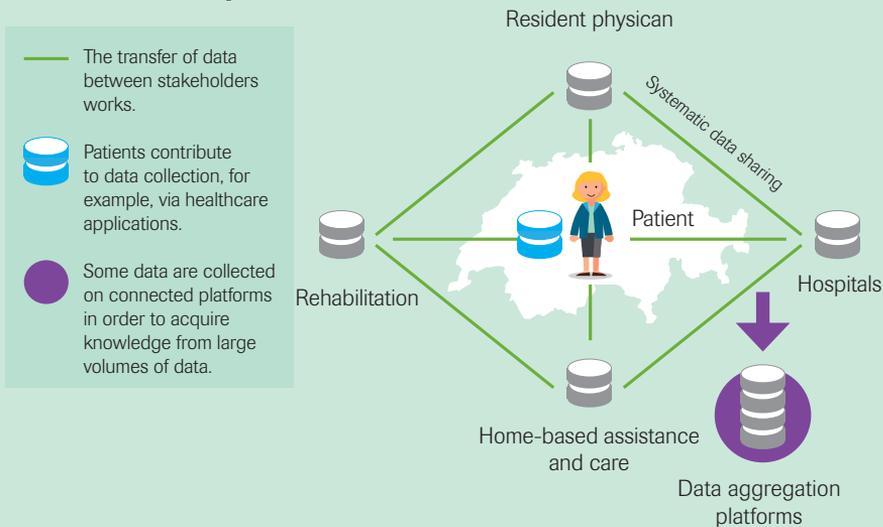
¹ Opt-Out means: a national medical electronic record is opened for each patient. Anyone who opposes this must unsubscribe.

Sharing patient data

Today: Potential of data not fully used



Vision: The systematic sharing of data optimally supports the treatment of patients



Source: Explanatory illustration from Roche Pharma (Switzerland) Ltd

“Society must be actively involved in the dialogue”

Dr. Brida von Castelberg, Vice-President of the Swiss Patient Organisation SPO Foundation and Dr. Yvonne Gilli, Specialist in General Internal Medicine and member of the Central Committee of FMH (Swiss Medical Association), take their positions in interviews.



Dr. Brida von Castelberg
Vice-President of the Swiss Patient Organisation SPO Foundation



Dr. Yvonne Gilli
Specialist in General Internal Medicine and member of the FMH's Central Committee

How do the public, patients and the medical community need to prepare for personalized healthcare?

Brida von Castelberg: “According to the current concept, personalized healthcare focuses first on medicinal personalization. A paradigm shift is indicated, because medicine only contributes to healthcare on a small scale. In their therapeutic choices, doctors have always taken into account not only the physical aspects but also the social and psychological factors and therefore they “personalise” each treatment in principle. We consider the quality of water, air and housing, but also

good working conditions to be obvious, whereas they have at least as much impact on our health and our quality of life as medicine. Consequently, it is necessary that the public have a concept of health that integrates and accepts these essential influencing factors, a concept according to which not everything can be treated, even with personalized healthcare. Life has an end, even with the most expensive personalized healthcare.”

Yvonne Gilli: “For me, the following question is crucial: As a doctor with ethical questions, how do we come to terms with, for example, the right not to know, managing the finitude of life and the question of knowing if extending life by two months is precisely worth doing? The consultancy activity of doctors becomes more complex and the requirements in terms of communication continually increase. Of course, the initial training and post-graduate education of all healthcare professionals should consider these aspects, but it is not sufficient. It is necessary that a broad and open reflection on this topic be initiated at the heart of our society. For example, in schools and universities, through an artistic exploration of the topic and media presence. Healthcare professionals play an essential role to enable this dialogue.”

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“The consultancy activity of doctors becomes more complex and the requirements in terms of communication continually increase.”

.....
- Yvonne Gilli
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Medical benefit is not directly synonymous to quality of life

For Brida von Castelberg, the reflection on new approaches for the evaluation of the benefit of medical treatments constitutes a core component in the discussion that must be engaged: “When a medicinal product is undoubtedly effective in a person, but is extremely expensive, it may not be acceptable in the end from a societal perspective. And the QALYs (Quality Adjusted Life Years) are fundamentally today the only method for evaluation. The only problem is that quality of life has a different meaning for each person: surviving one additional year while bedridden is not necessarily synonymous to quality of life.” In this context, Brida von Castelberg believes that it would potentially be preferable to pay people for an additional room for the rest of their lives to lighten living conditions slightly.

“Quality of life has a different meaning for each person.”

– Brida von Castelberg

As for Yvonne Gilli, she believes that universities and the FMH, but also patient organisations, have the responsibility to encourage and conduct parallel research independent of the industry in order to generate an extensive database to evaluate the benefit and therefore build trust towards the industry and personalized healthcare.

“We need national competence centres, registries and quicker access to innovative medicines”

Interview with Ruth Humbel, National Councillor, CVP and Chair of the National Council’s Social Security and Public Health Commission.



Ruth Humbel
National Councillor, CVP
and Chair of the National
Council’s Social Security
and Public Health
Commission

Today, personalized healthcare is already partly a reality and it will leave its mark even more strongly on therapeutic daily life in the future: What specific tasks do you deduce for politics?

Ruth Humbel: “Political priorities are currently transparency of quality, introducing the uniform funding of outpatient and inpatient services, the rectification of the funding of care, as well as cost control measures. Another specific project, which is strongly linked to personalized healthcare in some respects, is the implementation of the “National Action Plan for Rare Diseases”, which I called for almost ten years ago with the premise of “A national strategy to improve the medical situation of persons with rare diseases”.

In the new legislation, this involves accompanying the implementation of the action plan and, if necessary, to intervene in the Federal Council’s fields of action.”

What objectives does the “National Action Plan for Rare Diseases” pursue and what major intersections do you see with personalized healthcare?

Ruth Humbel: “The objective of the action plan was and is still that patients with rare diseases receive equivalent care throughout Switzerland. This involves early diagnosis and equitable access to effective treatments. In turn, this assumes that national competence centres, registries and optimised processes guarantee quick access to innovative medicines. This also holds true for personalized healthcare which, through the identification of specific biomarkers, no longer use standard treatments, but targeted individual treatments.”

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“Health data are certainly collected and saved but, except for the tumour registry, we have no national health registries.”

.....
– Ruth Humbel
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According to you, how should politics go about properly accompanying this development process?

Ruth Humbel: “For off-label treatments, which are for example commonly used in rare diseases or in personalized healthcare, the problem is that the delicate issue of covering the costs is delegated to the health insurers and they must decide on a

case-by-case basis. This complicates equitable access to treatments. In my opinion, it is necessary, particularly in this sector but also in general for expensive innovative treatments, that new reimbursement models allowing for quick access to innovative treatments are established in the laws or ordinances and that the pharmaceutical industry assumes a financial co-responsibility when the promised benefit does not materialise. This is the only method we have to sustainably resolve the conflict of objectives between, on the one hand, the costs of healthcare or health insurance premiums that are increasing and, on the other hand, quick access for patients to innovations. In my opinion, it is also necessary to act in terms of the authorisation and funding of gene and cell therapies. If these therapies are authorised by Swissmedic and recognised as a required service of health insurance by the FOPH, then the FOPH should also set their prices and it cannot delegate this task to health insurer.”

You discuss national competence centres. Are such centres realistic, in your opinion?

Ruth Humbel: “Defining national competence centres providing access to specialised care throughout Switzerland to all patients, specifically in the area of rare diseases, will not be easy due to our federal structures. In Switzerland, we do not have a national healthcare strategy. The healthcare sector falls within the jurisdiction of the cantons, which have the constitutional duty of guaranteeing healthcare for the population.

Indeed, it is necessary to have an inter-cantonal collaboration, which should be reinforced and which falls under the responsibility of the Conference of Cantonal Health Directors (GDK, Gesundheitsdirektorenkonferenz). For the stakeholders, impetus must be actively given at the cantonal or GDK levels, but national politics must support these aspirations.”

For the 2020–2030 priorities in terms of health policy, the Federal Council focuses on the four most pressing challenges:

- Technological and digital transformation
- Demographical and social evolution
- Maintaining high-quality care and a financially viable system
- The opportunity to live in good health

Digital transformation constitutes a new priority for the Federal Council: it wants to encourage digitisation and the use of data. At the same time, it wishes to initiate a societal discussion on the possibilities and risks related to new technologies. Furthermore, it has acknowledged that the coming of artificial intelligence and genetic engineering raise, for example, legal and ethical issues that society must confront.

Source: <https://www.bag.admin.ch/bag/de/home/strategie-und-politik/gesundheit-2030/gesundheitspolitische-strategie-2030.html>

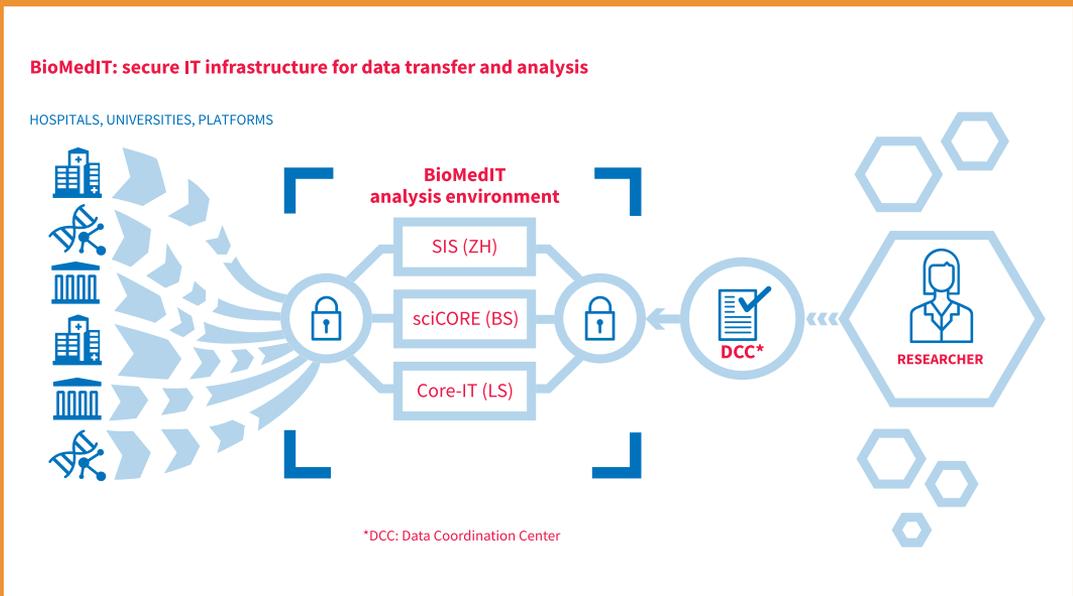
In addition, you are requesting the creation of a national health registry. What milestones do politicians want and must establish in order to advance in this field?

Ruth Humbel: “As this involves registries, there is great reluctance with respect to digitisation in the Swiss healthcare system. It is certain that data protection is essential in the sensitive field of health. However, it should not be taken advantage of to block transparency and technical progress. Health data are certainly collected and saved but, except for the tumour registry, we have no national health registries. Such registries must be created. And through technological possibilities, the data collected must be processed and used: by doctors and patients, to follow up with therapeutic successes and to monitor health developments; by researchers, in view of optimising therapeutic offers. The Federal Council established this aspect in its priorities in terms of health policy by 2030 (comment from the editorial team: see information box). It remains to be seen what progress could be accomplished in the next batch of legislation: it is necessary to keep in mind that, in our direct democracy, any modification of the law can be put to a referendum. This obliges the legislator to be cautious when he legislates on delicate topic.”

Das Swiss Personalized Health Network (SPHN)

The SPHN is a national initiative by the State Secretariat for Education, Research and Innovation (SERI) and by the Federal Office of Public Health (FOPH). It is managed by the Swiss Academy of Medical Sciences (SAMS) and the Swiss Institute of Bioinformatics (SIB). The objective of the initiative is to allow for the use of health data for research for all of Switzerland, i.e., beyond the boundaries of the different health institutions, via the establishment of harmonised standards. In doing so, the implementation, analysis, coordination and the validation of data infrastructures are

at the forefront. The strategy pursued by the SPHN is that data storage remains decentralised with the collecting authorities but that it is still ensured that data from different sources can be regrouped within the scope of specific research projects via appropriate sharing standards. The legal and ethical requirements are strictly followed. In order to respect, also on the technical level, the provisions pertaining to data protection and data security, the BioMedIT network was created for data analysis. This network is available to all research institutions in Switzerland.



BioMedIT: secure IT infrastructure for data transfer and analysis (source: Fact Sheet 2019, sphn.ch)

An essential element of the BioMedIT network is the Data Coordination Centre (DCC), which ensures the network's central services. When the requests for researchers to be able to use health data for their research comply with the ethical and security requirements, the data requested from hospitals (or other data providers) are pseudonymised and encrypted for the transfer. The requestor (recipient of the data) can then access the data on the BioMedIT network via his account. SPHN follows specific guidelines, such as, for example, the "Ethical Framework for Responsible Data Processing in the Swiss Personalized Health Network"¹ or the joint "Information Security Policy"². For the 2017–2020 period, the SPHN was attributed funds at CHF 68 million in order to create the basics required for sharing health

data on a national scale. Service agreements were concluded with five university hospitals. Furthermore, twenty-four other projects are supported with the SPHN's funds, of which six are funded in conjunction with the ETH. In total, thirty-three Swiss organisations and institutions are involved through the service agreements mentioned and/or supported projects. All decision-makers in the research, clinical, research promotion and patient organisation fields are involved in order to guarantee the project's sustainability and likely course.

1 https://sphn.ch/wp-content/uploads/2020/01/Report_20170825_Responsible-Data-Processing-in-Health-Research_SPHN-ELSlag.pdf

2 https://sphn.ch/wp-content/uploads/2020/01/sphn_information_security_policy_v1.pdf

SPHN's factors for success for personalized health research:

- Shared concept of the project's vision and scope
- Availability of all parties involved in the sharing of health data for the benefit of society (citizens, patients, hospitals, research institutions, etc.)
- Transdisciplinary approach with clinicians, researchers, bioinformaticians, experts in machine learning, etc.
- Interoperability of health data for all of Switzerland and data infrastructures coordinated on a national scale
- High-performing IT capacity in a safe and secure IT environment
- Innovation of processes in research and healthcare

Source: <https://sphn.ch/wp-content/uploads/2019/11/SPHN-Review-Fact-Sheet-2019-1.pdf>
Additional information: <https://sphn.ch>

Collecting data for health

Prof. Peter Meier-Abt, former Vice-Chair of the National Steering Board of the SPHN (Swiss Personalized Health Network) and Prof. Olivier Michielin, Head Doctor at the Oncology Department and Head of Precision Oncology Center at the CHUV, take positions in an interview.



Prof. Peter Meier-Abt
Former Vice-Chair of the National Steering Board of the SPHN (Swiss Personalized Health Network)



Prof. Olivier Michielin
Head Doctor at the Oncology Department, Head of Precision Oncology Center, CHUV (Lausanne University Hospital)

Personalized healthcare relies largely on data analysis. How do you see the role of doctors in the future?

Olivier Michielin: “Even if in the future diagnosis will increasingly rely on data analysis, it nevertheless still needs to be explained and discussed. I compare it to a CT scan: facing this very complex technology, the interpretation and emphatic discussion of findings with the patient remains an essential role for the doctor.”

Peter Meier-Abt: “Discussion with the patient, treatment planning and its implementation remain the core elements of medical activity. However, doctors are no longer the data holders. This

will be the case and, for example in the Netherlands, it has been customary for years that patients always have their data on them on a credit card. In this way, they are conferred with greater authority: they decide what should happen to their data.”

“Patients should be conferred greater authority in relation to their data, such as, for example, in the Netherlands, where they have their data on them on a credit card.”

– Peter Meier-Abt

What are the future challenges and opportunities of using health data in Switzerland?

Olivier Michielin: “Personalized healthcare strongly influences the evolution of medicine. If the current developments are based on traditional molecular and clinical data, new types of data may emerge, provided that there is evidence of their utility in care. An example is the use of connected devices: for some years, health data are increasingly being collected using smart phones and “intelligent” watches and bracelets. It is data collected by patients that, in addition to clinical data, may provide information – currently missing – on the environmental context, namely dietary habits, sleep patterns, pulse, blood pressure or physical activity. At the CHUV, we are launching a project to evaluate the clinical impact of the integration of data reported by patients. Thus, each patient becomes an active stakeholder and a data provider. He therefore directly contributes to the research in personalized healthcare.”

“Data collected by patients may provide information – currently missing – on the environmental context, such as, for example, dietary habits, sleep patterns, pulse, blood pressure, or physical activity.”

– Olivier Michielin

Peter Meier-Abt: “The patient is the key element. Today, the discussion is too focused on individual rights and data protection. The latter is guaranteed, since the data will never be saved centrally on a server of the SPHN, but will always remain where they were collected.

The SPHN establishes standards for sharing and coordinates it. Likewise, the industry never has direct access to the data. One centre that the SPHN has (DCC; implementation planned for 2024) will receive the requests coming from research and industry and will make the data available in a suitable form. It is now urgent to raise society’s awareness of the fact that everyone

benefits when each person makes his data available.”

What can Switzerland learn from other countries in respect to the use of health data?

Peter Meier-Abt: “The SPHN had set the objective of connecting between them all the university hospitals of Switzerland so that the data can be used both for improving patient care and for primary research and applied clinical research. This intermediate objective of the SPHN has now been reached. It is now a question of integrating the cantonal and regional hospitals, then all surgeries. For us, everything takes much time unfortunately; besides the FOPH, twenty-six stakeholders are still involved in the decision. Other countries, in particular Nordic and Anglo-Saxon countries, have decided based on a top-down mode to create a national cancer registry; today, they have highquality health data. Or in

Use of patient data in oncology: the example of a molecular tumour board

Oncology plays a pioneering role in the field of personalized healthcare through the vast knowledge acquired in genetics and the molecular biology of tumours. The Molecular Tumour Board makes it possible to discuss patient cases for which complex molecular data are available or for which a thorough molecular diagnosis seems interesting. Constituted from a group of interdisciplinary experts, the Molecular Tumour Board provides the most appropriate therapeutic strategies based on the assembly of individual data. The CHUV (Lausanne University Hospital) and the HUG (Hôpitaux Universitaires de Genève [University Hospitals of Geneva]) are very advanced in this field with a joint Molecular Tumour Board. Considering that a great deal of information on each patient is not saved centrally, the gathering of data is essential. For years, the CHUV has been collecting and analysing data on tumours and treatments. In the future, oncologists from the tumour board may consult not only the CHUV’s databank but also the data from other Swiss university hospitals obtained via the SPHN.

More information at www.precisionmed.ch

addition, there is Estonia: the country has benefited from the political transition to implement data sharing on a national scale. Furthermore, we have a large fragmentation in the clinical information systems. We can clearly allow ourselves to do this. In order to obtain valid data for research and development, we must all work together now. But time is passing quickly and political impetus would be essential in consequence.”

“It is now urgent to raise society’s awareness of the fact that everyone benefits when each person makes his data available.”

– Peter Meier-Abt

Oliver Michielin: “We have taken our time but we can catch up. Switzerland has good framework conditions because our medical and societal structure is relatively stable, which is beneficial for long-term data collection and analysis.”

Level of digitisation in the healthcare sector

Switzerland is ranked 14 according to the Bertelsmann Digital Health Index.

Instructions for reading: The table below shows the Digital Health Index, sorted according to the classification of different countries. The value of the Digital Health Index can be between 0 and 100, where the higher the level of development in the “Digital Health” field, the higher the value.

Ranking of countries according to the Digital-Health-Index

Rank		Digital-Health-Index	
1	Estonia	81.9	Group 1 > 70
2	Canada	74.7	
3	Denmark	72.5	
4	Israel	72.4	
5	Spain	71.4	
6	NHS England	70.0	Group 2 ≤ 70
7	Sweden	68.3	
8	Portugal	67.2	
9	The Netherlands	66.1	
10	Austria	59.8	Group 3 < 60
11	Australia	57.3	
12	Italy	55.8	
13	Belgium	54.7	
14	Switzerland	40.6	Group 4 < 50
15	France	31.6	
16	Germany	30.0	
17	Poland	28.5	
	Average	59.0	
	Standard deviation	16.9	

Source: Bertelsmann Foundation

https://www.bertelsmann-stiftung.de/fileadmin/files/Projekte/Der_digitale_Patient/VV_SHS-Gesamtstudie_dt.pdf
(p. 225)

“New reimbursement models are needed more than ever”

Overview of reimbursement mechanisms provided by Matthias Schenker, Director of the Health Policy Department, CSS Insurance and Remo Christen, Director of Market Access & Health Care Affairs, Roche Pharma (Switzerland) Ltd.



Remo Christen
Director of Market Access
& Health Care Affairs,
Roche Pharma
(Switzerland) Ltd



Matthias Schenker
Director of the Health
Policy Department, CSS
Insurance

Standardised reimbursement processes for personalized treatments – a field of tension?

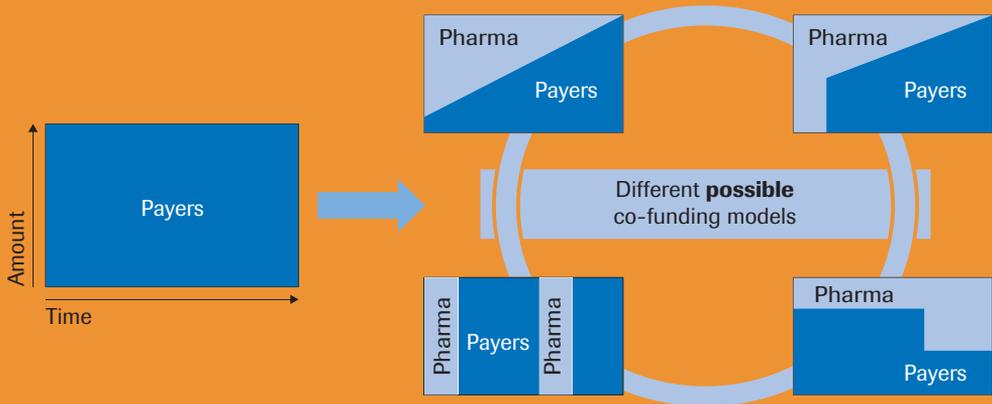
Both parties, health insurers and the pharmaceutical industry with a research activity, agree on a fundamental point: patients in Switzerland must today and in future have guaranteed access to innovative personalized treatments.

“For the moment, the current system is only partially able to follow the pace of the progress of medicine and to make modern treatments available for patients in a timely manner. Specifically,

personalized healthcare brings medical solutions to patients for whom the current authorisation and reimbursement processes are no longer sufficient”; that is how Remo Christen explains the situation. Today, the system operates according to the following principle: one medicinal product – one indication – one reimbursement. And even when a medicinal product has several indications, a distinct tedious process is required for each indication for the reimbursement via the list of proprietary medicinal products.

In future, for example in the field of cancer, medicinal products known as “tumour agnostics” will increasingly be on the market under the personalized healthcare label. These medicinal products target the genomic and molecular characteristics of cancer, regardless of the type of cancer or the location of the cancer in the body. Furthermore, with the increasing analysis of data related to healthcare (real-world data) and with the linking of medical knowledge, it will be increasingly possible to find new indication areas for medicinal products without having to conduct standard clinical studies. The system must prepare for it. Today already, there are medicinal products on the market that are used beyond the authorised indications based on scientific knowledge (“scientific rationale”) and the continuously increasing experience of experts.

Possible risk-sharing models between the pharmaceutical industry and health insurers



Source: Explanatory illustration from Roche Pharma (Switzerland) Ltd

“Sharing risks is the catchword. In the future, pharmaceutical companies must assume the financial risk more, until enough evidence of the efficacy of a treatment is available.”

– Matthias Schenker

Currently, the system may react to this situation with Article 71 a-d of the KVV (see information box). This article allows for access to innovative medicines outside the standard of care in a timely manner and, on a case-by-case basis, covered by mandatory health insurance. “The main problem with Article 71a-d of the KVV is, however, that there are a lot of exceptions,” stated Matthias Schenker. This is problematic: the administrative burden for individual cases is very high, as the funding of a treatment must be negotiated almost on a case-by-case basis. And it increases: the number of cases for which Art. 71a-d of the KVV ap-

plies has doubled during these last four years for CSS Insurance, increasing from 3,000 to 6,000.

How should authorisation therefore be regulated in the context of medicine that is increasingly personalized? And also reimbursement in particular?

To resolve this problem, the two experts believe that there is an urgent need to act with regard to the law and the ordinance. Matthias Schenker’s call is simple: “At the same time for the authorisation by Swissmedic and for the reimbursement by the FOPH, more flexible criteria and new models of funding must be introduced so that we can react to rapid scientific progress.”

For Remo Christen, it is also necessary to rethink the evaluation of the benefit of treatments and he has formulated specific proposals for this purpose. The benefit of a new treatment could, for example,

“Funding” perspective

be evaluated temporarily by a scientific committee of experts and a temporary price could be set so that patients can have access to it starting from the day of the authorisation. The final price would then be determined based on the evidence generated via the data collected and analysed in parallel.

“Personalized healthcare brings medical solutions to patients for whom for the current authorisation and reimbursement processes are no longer sufficient.”

– Remo Christen

Specifically, the funding of modern medicine is a field where the different stakeholders must review their positions. Personalized treatments have the potential to take a weight off the system overall, but they are also often at the heart of intensive discussions on costs. “Sharing risks is the catchword,” considered Matthias Schenker; and he added that “In the future, pharmaceutical companies must

assume the financial risk more, until enough evidence of the efficacy of a treatment is available.” In his opinion, this is the only way for the healthcare system to be ready to support a fair price for a highly effective medicinal product. For Remo Christen, it is clear that this is the way of the future: “The most varied models are possible, such as milestone payments, advance payment, or a gradual coverage of costs as therapeutic success progresses. What is important is that in such models also, scientific reflection is central.” Both speakers are unanimous: It is only with an attitude focused on finding solutions on behalf of the pharmaceutical industry, the health insurers and the authorities or the political sphere that personalized treatments will be accessible for all in the long term and fundable on the basis of solidarity. And finally, with the words of Remo Christen: “What is essential is the dialogue with the objective of allowing all patients from Switzerland to have access to modern medical care.”

Article 71a-d of the Health Insurance Ordinance (KVV)

Article 71 a-d of the KVV regulates the coverage of the costs of authorised medicinal products that are used outside their area of indication or that are not included in the list of proprietary pharmaceutical products. Medicinal products that are not authorised in Switzerland and that must be imported also fall under the jurisdiction of the scope of Article 71a-d of the KVV. The costs are covered under the condition that this involves potentially fatal or severe and chronic diseases, that there are no therapeutic or authorised alternatives, that using the treatment makes it possible to count on a high therapeutic benefit and that the ratio between the therapeutic benefit and the cost is appropriate. The objective of this article from the ordinance is to allow patients to benefit from new therapeutic possibilities in individual cases and after the granting of coverage by health insurers.

Summary

- Personalized healthcare is a topic that brings out much hope, expectations and challenges for patients, doctors, the industry and the healthcare system. The involvement of all stakeholders proves to be even more necessary to continue to advance personalized healthcare in Switzerland.
- In this publication, representatives from academia and research, the medical community, patient organisations, the political sphere, health insurance and the industry address this multifaceted topic based on their respective perspective.
- The different articles focus, among other things, on the issues of societal needs, funding, political and regulatory policy and the importance of digital progress for medicine.
- This brochure should allow for an active interdisciplinary reflection on this topic and the identification of common fields of action. It should therefore contribute to the additional establishment of personalized healthcare in daily clinical practice in Switzerland.