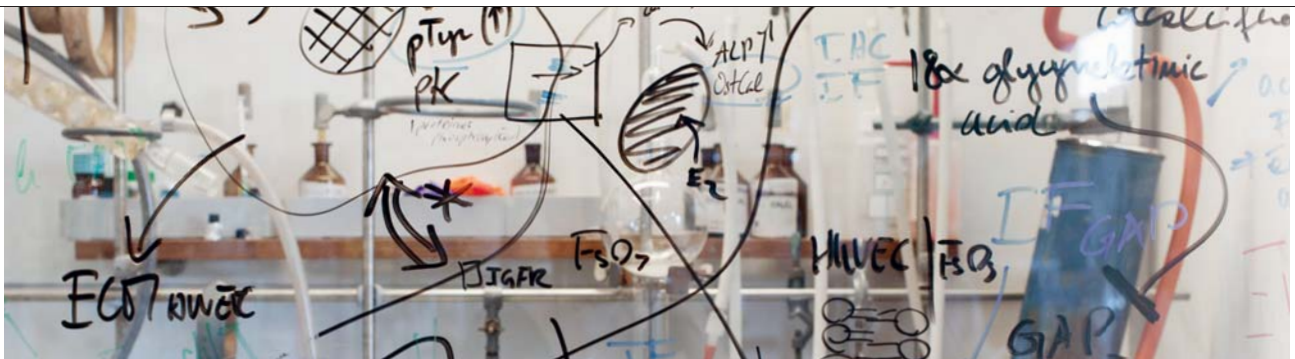


SSIC Report 1/2015

# Trends in Biomedical Research

Report and Recommendations by the Swiss Science and Innovation Council SSIC



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Schweizerischer Wissenschafts- und Innovationsrat  
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Swiss Science and Innovation Council

## The Swiss Science and Innovation Council

The Swiss Science and Innovation Council SSIC is the advisory body to the Federal Council for issues related to science, higher education, research and innovation policy. The goal of the SSIC, in line with its role as an independent consultative body, is to promote a framework for the successful long term development of Swiss higher education, research and innovation policy.

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Der Schweizerische Wissenschafts- und Innovationsrat SWIR berät den Bund in allen Fragen der Wissenschafts-, Hochschul-, Forschungs- und Innovationspolitik. Ziel seiner Arbeit ist die kontinuierliche Optimierung der Rahmenbedingungen für die gedeihliche Entwicklung der Schweizer Bildungs-, Forschungs- und Innovationslandschaft. Als unabhängiges Beratungsorgan des Bundesrates nimmt der SWIR eine Langzeitperspektive auf das gesamte BFI-System ein.

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Le Conseil suisse de la science et de l'innovation CSSI est l'organe consultatif du Conseil fédéral pour les questions relevant de la politique de la science, des hautes écoles, de la recherche et de l'innovation. Le but de son travail est l'amélioration constante des conditions-cadre de l'espace suisse de la formation, de la recherche et de l'innovation en vue de son développement optimal. En tant qu'organe consultatif indépendant, le CSSI prend position dans une perspective à long terme sur le système suisse de formation, de recherche et d'innovation.

## Il Consiglio svizzero della scienza e dell'innovazione

Il Consiglio svizzero della scienza e dell'innovazione CSSI è l'organo consultivo del Consiglio federale per le questioni riguardanti la politica in materia di scienza, scuole universitarie, ricerca e innovazione. L'obiettivo del suo lavoro è migliorare le condizioni quadro per lo spazio svizzero della formazione, della ricerca e dell'innovazione affinché possa svilupparsi in modo armonioso. In qualità di organo consultivo indipendente del Consiglio federale il CSSI guarda al sistema svizzero della formazione, della ricerca e dell'innovazione in una prospettiva globale e a lungo termine.

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Report and Recommendations by the Swiss Science  
and Innovation Council SSIC

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Adopted by the Council on the 11<sup>th</sup> of November 2014



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# Executive Summary

## Zusammenfassung

## Résumé

**E** The Swiss Science and Innovation Council (SSIC) is conducting a survey on the status of biomedical research. In this report it analyses recent developments in this scientific field, which is of major importance for Switzerland, and reflects on the potential implications of these developments for the organisation of public and private research.

In a first step, the notion of “biomedical research” is defined, as the meaning of the term differs depending on its users, leaving room for misunderstandings. Rather than viewing it as a concept, the SSIC sees the term as an open notion encompassing the full range of scientific approaches directly or potentially aiming towards medical application. As a result, the disciplinary boundaries of the biomedical domain cannot be clearly defined, while its core is clearly identifiable. Initially understood as forming a bridge between medicine and the natural sciences, and later also with the technical sciences, biomedicine is now beginning to include practices and approaches developed by the human and social sciences. These disciplines help explain in particular the epistemological premises in biomedical research and highlight a process in which the notion of “health” is redefined as a “subjective and social construct”. With their hopes raised by research, individuals and nations are investing a growing part of resources in aiming for this increasingly demanding goal.

On the one hand, the expansion of biomedical research may be seen as leading, at least in part, to a lack of sustainability in health systems. On the other hand, increasing needs and demands, coupled with a less rapid rise in the number of medical professionals, exert considerable pressure on medical faculties, teachers and researchers, as any minute not devoted to delivering care has to be accounted for.

Between “scientification” of medicine and “medicalisation” of science, the relationship between researchers and clinicians constitutes another key challenge for biomedicine. This interaction is vital to the success of translational research, that is to say, the transfer of knowledge from one scientific domain to another. Interdisciplinary dialogue should highlight the respective specificities, and in particular the requirements

inherent to clinical research stemming from its specific purpose and context. For several decades now, biomedical research in Switzerland has been marked by numerous attempts to bring researchers together and ease cooperation across disciplines and institutions. There have also been attempts to establish closer links between public and private research. Despite these efforts, communication between researchers from different scientific backgrounds remains problematic.

The third problem, the “applicability” of scientific knowledge, is a challenge in all types of research, but is of particular intricacy in the biomedical field. Many researchers whose scientific inquiry actually focuses on basic science claim to be engaged in biomedical or translational research. It is vital to appreciate progress in knowledge and technologies without limiting their potential scope to medical applications. On the other hand, one has to be aware of phenomena which prevent innovations from gaining ground in the biomedical field, in particular publication bias, the issue of reproducibility and the effects of mainstreaming.

In consideration of the trends and challenges mentioned above, the SSIC formulates a series of recommendations for those authorities and institutions in charge of the promotion and regulation of biomedical research:

- terms which suggest applicability, such as “biomedical” or “translational”, should be used only sparingly in the context of science policy;
- appropriate criteria must be evolved for assessing clinical research;
- all researchers must be given access to the best expertise and infrastructure in the form of inter-institutional exchanges, such as between hospitals and medical schools, technical and cantonal universities;
- an attitude of openness should be fostered favouring research outside of the mainstream and the creation of innovative start-ups;
- the terms and objectives should be clarified in all types of public-private-partnerships.

D

Der Schweizerische Wissenschafts- und Innovationsrat (SWIR) befasst sich mit dem Stellenwert der biomedizinischen Forschung. Im vorliegenden Bericht analysiert der SWIR die neuesten Entwicklungen in diesem für die Schweiz bedeutenden wissenschaftlichen Bereich und stellt Überlegungen zu den allfälligen Auswirkungen auf die Organisation der öffentlichen und privaten Forschung an.

In einem ersten Schritt soll die Bedeutung der Bezeichnung «biomedizinische Forschung» geklärt werden. Sie ändert sich in Abhängigkeit vom Personenkreis, der sie verwendet, und gibt Anlass zu Missverständnissen. Der SWIR betrachtet «biomedizinische Forschung» nicht als ein abschliessend definiertes Konzept, sondern als eine offene Bezeichnung, die sämtliche wissenschaftlichen Ansätze umfasst, die auf eine reale oder mögliche medizinische Anwendung zielen. Somit können die disziplinären Grenzen der Biomedizin nicht definitiv festgelegt werden, während sich ihr Kern leicht erkennen lässt. Die Biomedizin, die zunächst als eine Annäherung zwischen der Medizin und den Naturwissenschaften, dann auch den technischen Wissenschaften verstanden wurde, beginnt, Praktiken und Ansätze aus den Geistes- und Sozialwissenschaften zu integrieren. Diese klären insbesondere die erkenntnistheoretischen Prämissen der biomedizinischen Forschung und erhellen den Prozess der Neubestimmung von «Gesundheit» als eine «subjektive und soziale Konstruktion». Unter dem Eindruck der durch die Forschung hervorgerufenen Hoffnungen investieren Einzelpersonen und Industrienationen einen wachsenden Anteil ihrer Ressourcen in dieses immer anspruchsvollere Ziel.

Einerseits lässt sich die mangelnde Nachhaltigkeit der Gesundheitssysteme teilweise durch den Aufschwung der biomedizinischen Forschung erklären. Weil die Anzahl medizinischer Fachleute nicht im gleichen Mass ansteigt, üben andererseits die steigenden Bedürfnisse und Anforderungen einen hohen Druck auf die medizinischen Fakultäten sowie auf die Dozierenden und Forschenden aus, weil jede nicht der Patientenpflege gewidmete Minute besonders zu rechtfertigen ist.

Im Spannungsfeld zwischen der «Verwissenschaftlichung» der Medizin und der «Medikalisierung» der Wissenschaft stellt das Verhältnis zwischen den Forschenden, die von den Grundlagenwissenschaften her kommen, und den Ärztinnen und Ärzten in der Klinik eine zweite für die Biomedizin bedeutende Herausforderung dar. Diese Wechselbeziehung ist unentbehrlich für den Erfolg der translationalen Forschung, das heisst für die Übertragung der Kenntnisse von einem Wissensgebiet in ein anderes. Die spezifischen Aspekte der klinischen Forschung, insbesondere die ihr aufgrund ihres Gegenstandes und Umfelds inhärenten Bedingungen, müssen durch einen interdisziplinären Dialog herausgearbeitet werden. Seit mehreren Jahrzehnten wird die biomedizinische Forschungslandschaft in der Schweiz von zahlreichen Initiativen geprägt, welche die Forschenden einander annähern und ihre interdisziplinäre und interinstitutionelle Zusammenarbeit sowie die Kooperation zwischen dem öffentlichen und privaten Bereich erleichtern sollen. Trotz dieser Anstrengungen bleibt die Kommunikation zwischen Forschenden mit unterschiedlichem wissenschaftlichem Hintergrund schwierig.

Die dritte Problematik betrifft die «Anwendbarkeit» der wissenschaftlichen Erkenntnisse. Sie stellt für jede Art von Forschung eine Herausforderung dar, doch auf dem Gebiet der Biomedizin erhält sie eine besondere Dringlichkeit. Zahlreiche Forschende, deren wissenschaftliche Fragestellungen auf Grundlagenkenntnisse ausgerichtet sind, verweisen darauf, dass sie einen biomedizinischen oder sogar translationalen Ansatz verfolgen. Bei der Bewertung des wachsenden Umfangs der Kenntnisse und Techniken darf deren Tragweite auf keinen Fall auf die Möglichkeit einer medizinischen Anwendung beschränkt werden. Vielmehr sind Aspekte zu berücksichtigen, welche die Entwicklung von biomedizinischer Innovation bremsen. Dazu gehören namentlich der «Publikationsbias», die Frage der Reproduzierbarkeit und die Mainstreaming-Effekte.

Aufgrund dieser Überlegungen richtet der SWIR eine Reihe von Empfehlungen an die Behörden und Institutionen, die mit der Förderung und Reglementierung der biomedizinischen Forschung betraut sind:

- Bezeichnungen wie «biomedizinisch» oder «translational», die unbestimmte Versprechungen für Anwendungen suggerieren, sollen mit Vorsicht und sparsam verwendet werden;
- angemessene Kriterien zur Beurteilung der klinischen Forschung sollen ausgearbeitet werden;
- durch interinstitutionellen Austausch zwischen Spitälern und medizinischen Fakultäten sowie zwischen den Eidgenössischen Technischen Hochschulen und den Universitäten soll allen Forschenden der Zugang zu den besten Kompetenzen und Infrastrukturen ermöglicht werden;
- durch eine offene Haltung sollen die Gründung innovativer Unternehmen sowie eine Forschung, die ausgetretene Pfade verlässt, gefördert werden;
- Bedingungen und Ziele für Partnerschaften zwischen öffentlicher und privater Forschung sollen geklärt werden.

## F

Le Conseil suisse de la science et de l'innovation (CSSI) mène une réflexion sur le statut de la recherche biomédicale. Il analyse dans le présent rapport les développements récents de ce domaine scientifique d'une importance majeure pour la Suisse et réfléchit à leurs implications potentielles pour l'organisation de la recherche publique et privée.

La première étape consiste à clarifier la notion de «recherche biomédicale», dont la signification diffère en fonction des usagers et se prête à certains malentendus. Plutôt que comme un concept, le CSSI l'envisage comme une notion ouverte, regroupant l'ensemble des approches scientifiques dirigées vers une application médicale actuelle ou potentielle. En conséquence, les frontières disciplinaires du domaine biomédical ne peuvent être tracées de manière définitive, tandis que son centre est facilement identifiable. D'abord comprise comme le rapprochement de la médecine avec les sciences naturelles, puis avec les sciences techniques également, la biomédecine commence à intégrer des pratiques et approches issues des sciences humaines et sociales. Ces disciplines éclairent notamment les prémisses épistémologiques de la recherche biomédicale et mettent en lumière un processus de redéfinition de la notion de «santé» en tant que «construction subjective et sociale». Sous l'effet des es-

poirs suscités par la recherche, les individus et les nations industrialisées investissent une part croissante de leurs ressources en faveur de cet objectif toujours plus exigeant.

D'une part, le manque de durabilité des systèmes de santé peut être considéré comme en partie lié à l'essor de la recherche biomédicale. D'autre part, l'accroissement des besoins et des demandes, conjugué à l'augmentation plus lente du nombre de professionnels médicaux, exerce de fortes pressions sur les facultés de médecine et les enseignants-chercheurs, dès lors que chaque minute qui n'est pas dévolue aux prestations de soins doit être justifiée.

Entre «scientification» de la médecine et «médicalisation» de la science, la relation entre chercheur issu des sciences fondamentales et clinicien constitue un deuxième enjeu central pour la biomédecine. Cette interaction est indispensable au succès de la recherche translationnelle, c'est-à-dire à l'activité de traduction des connaissances d'un domaine du savoir vers l'autre. Le dialogue interdisciplinaire doit permettre une mise en lumière des spécificités, et notamment des conditions inhérentes à la recherche clinique en raison de son objet et de son contexte particuliers. Depuis plusieurs décennies, le paysage de la recherche biomédicale suisse a été marqué par de nombreuses initiatives visant à rapprocher les chercheurs et à faciliter leur collaboration au-delà des disciplines et des institutions, ainsi qu'entre les secteurs public et privé. Malgré ces efforts, la communication entre chercheurs issus de cultures scientifiques différentes reste difficile. La troisième problématique de l'«applicabilité» du savoir scientifique représente un défi pour toute forme de recherche, mais se pose avec une intensité particulière dans le domaine biomédical. Beaucoup de chercheurs dont le questionnement scientifique est axé sur la connaissance fondamentale se présentent comme engagés dans une approche biomédicale, voire translationnelle. Il est indispensable d'apprécier l'expansion des savoirs et des techniques sans limiter leur portée à la possibilité d'une application médicale. En revanche, des phénomènes freinant le développement de l'innovation dans le domaine biomédical doivent être pris en compte, notamment le biais de publication, la question de la reproductibilité et les effets de *mainstreaming*.



Sur la base de ces réflexions, le CSSI formule une série de recommandations à l'attention des autorités et des institutions chargées d'encourager et de réguler la recherche biomédicale:

- Un usage parcimonieux de termes porteurs d'une vague promesse d'application tels que «biomédical» ou «translationnel», dans le contexte de la politique scientifique;
- Le recours aux critères adaptés pour juger de la recherche clinique;
- Le souci d'assurer à tous les chercheurs l'accès aux meilleures compétences et infrastructures au travers d'échanges interinstitutionnels, que ce soit entre les hôpitaux et les facultés de médecine, ou entre les écoles polytechniques et les universités;
- Une attitude ouverte privilégiant la recherche s'écartant des sentiers battus et la création d'entreprises innovantes;
- Une clarification des termes et objectifs communs lors des partenariats entre la recherche publique et privée.

# Part

# One

Theses and

Recommendations

## Theses

In the theses and recommendations that follow, the SSIC offers proposals that are also intended to encourage greater reflection in other types of works, as to how to address the current challenges in biomedical research and how to conceive public funding in this field. Because of the wide range of the biomedical field, particular attention is paid to issues relating to biology and medicine, although recent developments in medical technology and other areas of knowledge are also considered. The majority of the recommendations are addressed primarily at the federal authorities, though some – concerning the organisation of university structures – are the joint responsibility of the cantons and the federal government. The SSIC does not claim to be in a position to resolve all the questions linked to this complex issue, but rather hopes to create the basis for a fruitful discussion among all those involved in biomedical research in Switzerland, in particular the different federal authorities responsible for regulation and funding in this area.

### T.1 “Biomedicine” as an open notion

Biomedicine results from combining practices and approaches from biology and medicine in the first place, completed by a growing number of natural and technical disciplines. The SSIC is convinced that the diversity of the Swiss biomedical research landscape reflects the flexibility and openness inherent to the notion of “biomedicine”, which is fundamentally dynamic and interdisciplinary. The apparent lack of homogeneity is the first condition for the success of this field, contrary to the reductionist view that sees biomedicine as a new discipline that should be encouraged to develop in a particular direction with the help of specific programmes.

### T.2 Basic and applied nature of biomedical research<sup>1</sup>

Most biomedical research activities in Switzerland aim to understand the fundamental mechanisms and functions of living matter. Discoveries often contribute to a greater basic knowledge while they at the same time help to find solutions to medical issues. Because it describes the transmission of knowledge from one discipline to another, and its relevance in both scientific and clinical terms, the notion of “translational research” expresses this double nature.

### T.3 Strength of biomedicine in Switzerland

Basic biomedical research in Switzerland is acknowledged as being excellent. Most experts currently place the quality of clinical research at international level. Private-sector biomedical research, and pharmaceutical companies in particular, account for a major portion of national spending on research and development. Although the system is thriving overall, the SSIC identifies certain trends which may quickly translate into new challenges for biomedical research.

<sup>1</sup> In its report on the “economisation” of science, (SSTC document 4/2013, pp. 26 and 45), the SSTC explores more closely the implications of the dual nature of biomedical research, notably its double impact in terms of basic knowledge and practical application.

## Recommendations

### 1 Preserve the autonomy of basic research

Focusing too closely on the potential applications may lead to the conclusion that funds invested in biological research and other natural and technical sciences – unless they soon lead to therapeutic treatments – are being thrown away. However, the excellence of basic research, in particular in the life sciences, is generally recognised as a key element in the success of scientific research in Switzerland. Developing knowledge and increasing our understanding of the world must remain research objectives in their own right. This task primarily falls to the public sector – science-based industry attributes considerable importance to the quality of basic academic research. The first recommendation is thus addressed both to the SNSF, which is responsible for evaluating public research projects, and to the SERI, whose work involves drawing up and selecting national programmes and initiatives, in particular within the context of the federal ERI dispatches.

#### **R.1 Public funding in basic research must be based on an assessment of its scientific merits. Expected application is not a criterion.**

If scientists interested primarily in basic research feel obliged to attach the label “biomedical” to their work in order to attract funding, they risk exposing themselves to being criticised for a lack of productivity, since the latter is directly linked with biomedicine in the collective mind. The disciplines concerned, however, are already increasingly subject to a process of “economisation”,<sup>2</sup> which threatens to impoverish the quality and originality of research. This trend may be increased by the generalised use of the term “biomedicine” when discussing research policy.

### 2 Reevaluate clinical research

Over the past decade, targeted measures deployed to promote clinical research in Switzerland have begun to bear fruit. Clinical researchers now have access to a range of funding sources and publish their results in high-quality international journals. However, the quality of research cannot be assessed simply on the basis of bibliometric indicators. Applicability is a legitimate criterion for clinical research and should indeed be accorded greater significance than it enjoys today.

#### **R.2.1 Standards and criteria applied to assess clinical research should be redefined and expanded.**

In addition to meeting the usual scientific standards, clinical research must conform to specific criteria, including ethical, organisational and formal criteria, which distinguish it from basic biomedical research. First, it is necessary to extend assessment practices to include more than the mere use of bibliometric indicators, for example peer review. Furthermore, efforts should be made to assess the dissemination of published results, for example in the issuance of clinical guidelines. Whether clinical research can be applied should also be asked at other levels, such as health services and medical practice.

#### **R.2.2 The SSIC invites medical faculties to work with the SNSF in drawing up a strategy to give greater value to the participation of clinical researchers in multicentre large-scale studies.**

Large-scale clinical trials are of increasing interest for the advance of medical knowledge. These international undertakings result in a small number of scientific articles co-signed by a long list of authors, from which it becomes impossible to assess the actual contribution of individual researchers according to bibliometric indicators. At present, participation in such clinical research projects is insufficiently valued in medical faculties, notably by evaluators from the fundamental disciplines, and especially in academic promotion procedures.

2 Cf. SSTC document 4/2013.

**R.2.3 The authorities responsible for clinical trial registers must establish a system for monitoring clinical studies not resulting in a scientific publication and draw up measures to reduce the number of such studies.**

In order to assess the quality of clinical research in a comprehensive manner, it is essential to be aware of the number of clinical research projects now listed in the new federal database not leading to publication in the five years following the completion of the trial. The proportion of unpublished results, if it turns out to be significant, should be taken into account in any future revision of legislation regarding research on human beings. Possible measures to reduce the publication bias of clinical studies based in Switzerland should be taken in conjunction with similar efforts at international level. If it is not practicable to publish negative research results in traditional scientific journals, the use of new communication formats such as platforms for exchanging scientific results should be systematised.

### 3 Promote translational research

For translational research to be successful, it needs to better integrate research practices from different disciplinary cultures; for instance, by a closer cooperation between medical faculties and other faculties or with a university hospital. For example, in recent years, a desire to promote constructive exchange between the two disciplines in the academic field has been reflected in the establishment of closer links between biology and medicine in some cantonal universities. It is clear that scientific collaboration thrives not just as a result of available structures, but primarily thanks to the motivation of researchers, their open-mindedness and the time at disposal for research and the communication of their experiences.

**R.3.1 The relevant authorities must clarify institutional relations between university hospitals and universities.<sup>3</sup>**

Relations between medical faculties and university hospitals are frequently very close, involving institutional and scientific overlaps which can lead to open or latent conflict. Without losing this proximity, the respective missions of the two types of institution should be clarified and a better profile for new professorial chairs established, in particular in the clinical disciplines. Rather than looking for personalities who are able to fulfil all tasks and please anybody, medical faculties should aim to establish a number of clinical chair positions mainly devoted to research and the training of their younger colleagues for conducting research.

<sup>3</sup> Cf. 4.2.3, p. 27. On the need for professorships involving a set amount of time devoted to research, see in particular the recommendations of the working group “Young academics for clinical research in Switzerland” of the Platform “Future of medical training”.

### **R.3.2 Medical faculties should develop inter-institutional exchange while preserving their academic identity and favoured links with other faculties.<sup>4</sup>**

The task of medical faculties is to introduce future physicians to as broad a scientific approach as possible, one which is both humanist and takes into account the full biological complexity of the patient. Medical faculties should therefore not be conceived of as vocational schools outside the academic system. Links between university departments should ensure that future doctors can communicate in depth with colleagues from the natural, social and human sciences. Likewise, the introduction of new curricula in technical environments, such as the *ETH Medical Strategy*<sup>5</sup>, emphasises the crucial role played by the engineering sciences in biomedical research; technical imaging and information technology come to mind in this context. This cooperation benefits the whole of the education, research and innovation system, provided that the same conditions exist for developing biomedical disciplines to the same level of excellence in both the cantonal universities and the federal institutes of technology. Similarly, cooperation initiatives between medical faculties and health departments in universities of applied sciences must be developed.

### **R.3.3 Federal support of research networks should follow a bottom-up strategy.<sup>6</sup>**

Research partnerships are formed according to the intellectual affinities and expertise requirements of a given project. These links must be easy to create, both across institutions and between disciplines, and researchers must remain primarily responsible for initiating this kind of cooperation. In the medium term, research networks thus formed do not necessarily need to be institutionalised, but rather should their structure reflect the dynamics of the research. In research networks receiving federal subsidies, the categories of players involved should be defined in as broad and inclusive a manner as possible in order to abide by the open notion of the term “biomedicine”.

## **4 Promote innovative research**

Private investment and public expectations exert unprecedented pressure on biomedicine, and this can have a negative impact on innovation. Academic researchers are encouraged to explore circumscribed research projects which result in incremental progress. In science-based innovation, a form of risk aversion is inhibiting the creation and – particularly in Switzerland – the growth of new private enterprises.

### **R.4 The SNSF and CTI, together with private-sector actors in research funding, must develop measures to reward radically ambitious research or development projects.<sup>7</sup>**

The SSIC underlines the crucial role of public institutional funding in ensuring the freedom of academic research. Moreover, in the current context, it believes it is necessary to establish a form of funding which rewards risk-taking, aimed at both basic and applied research. Such a mechanism, which should be open to all disciplines, would be designed on a modest scale and reserved for radically new approaches. The funding period would depend on individual project specifications and it should remain possible to suspend funding at short notice if a project fails, without prejudice to the careers of those involved. In the field of applied research, the ongoing dialogue between the SNSF and the CTI shall play a leading role in funding projects with a riskier outcome. Furthermore, the CTI should establish a monitoring of private enterprises that file for bankruptcy (especially in biotechnology) to analyse whether the potential of the researchers and entrepreneurs involved is sufficiently exploited, and if suitable individuals are provided with another research opportunity.

4 Cf. SSTC document 1/2006, pp. 10–11.

5 See footnote 45, p. 27.

6 See Box 1, p. 18, and 4.2.2, p. 27.

7 See point 4.3.3, p. 32.

## 5 Clarify the conditions for public-private research cooperation

Scientific cooperation between higher education institutions, hospitals and private enterprises is vital to biomedical innovation. Academic researchers cannot guarantee the development of new therapies without the support of the private sector. The private biomedical industry is more than ever dependent on the basic research work carried out in public laboratories on the one hand, and on collaboration with hospitals for conducting clinical trials on the other. However, when clinicians cooperate with private-sector researchers, this is often suspected from the outset of being against public interest, thus preventing the direct and informal dialogue that is the very principle of fruitful scientific cooperation.

**R.5 For cooperation between researchers in the public and private sectors to take place, their respective competency needs to be established. This can be achieved by clearly communicating the joint terms and objectives of cooperation.<sup>8</sup>**

Already at the time of signing a cooperation agreement, the objective should be set to publish the scientific results, even if these should prove to be contrary to the interests of the study's sponsors. It should be established whether either partner can request to change the focus of research, and if the academic researchers may exploit aspects considered unprofitable by the private partner. Development agreements between hospitals and medical technology companies should establish clear scientific rules for testing new devices, similar to those that govern clinical drug trials.

<sup>8</sup> See also recommendation 5 in the report on the "economisation" of science (SSTC document 4/2013).

# Part Two

## Report



# 1 Introduction

## 1.1 Context

Biomedical research has enjoyed several decades of exceptional standing in the scientific arena, both for the hopes it raises, the amount of funding it attracts and its ability to represent “science” in the collective mind. In 2012, over 41 percent of research funds allocated by the Swiss National Science Foundation (SNSF) went towards work carried out in the disciplinary fields of biology and medicine;<sup>9</sup> the majority of industrialised countries have a similar allocation.<sup>10</sup> However, a notable aspect of support for biomedical research in Switzerland is the considerable contribution by the private sector to national R&D activities, and in particular the leading role played by the pharmaceutical industry, along with many small to medium-sized enterprises (SMEs) specialising in health technology.<sup>11</sup>

The Swiss public and national authorities are thus involved in biomedical research on a number of levels, which may be standing in contradiction to each other in a number of aspects. On one hand, it is hoped that public research funding and investment in private research will lead to decisive scientific advances, generating jobs and high value-added products. On the other hand, citizens are potential patients who expect research to provide solutions to all kinds of public health issues, while seeking to control costs. Finally, the Swiss public is strongly in favour of promoting free basic scientific research.<sup>12</sup> These expectations and interests are reflected in the ways in which research and training are organised, such that the national landscape of biomedicine is constantly reshaped, in particular in order to make room for new players.

The SSIC is aware of the high quality of biomedical research in Switzerland, as well as of the private sector's and society's considerable degree of involvement in biomedical researchers' scientific activity. It therefore considers it necessary to reflect further on the meaning of “biomedicine” as well as on the trends in its development since the 2000s. This is why the Council's work programme (SSTC, 2012) included a project aiming at defining the field of biomedical research from a

disciplinary and institutional point of view, at investigating the role of the private sector as a partner and promoter of biomedical academic research, and, finally, at discussing whether an implicit promise of medical application should provide legitimacy to research activities.

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9 Cf. SNSF (2013), 2012 Annual Report, Bern, SNSF, p. 25.

10 The proportion of public funding is almost identical in Switzerland, Germany and Austria (2012 annual report of the Deutsche Forschungsgesellschaft, Aufgaben und Ergebnisse, p. 161; and the 2012 annual report of the Fonds zur Förderung der wissenschaftlichen Forschung, p. 73). In contrast, France's Agence Nationale de la Recherche apparently only devotes one tenth of its funds to biomedical research (ANR 2012 annual report, p. 12 and pp. 236–237) while in the US, the National Institutes of Health (NIHs) have a budget which is considerably larger than that of the National Science Foundation (Research America, U.S. Investment In Health Research 2011, p. 3).

11 In 2008, Swiss companies spent CHF 12 billion on R&D, of which CHF 4.6 billion was in the pharmaceutical industry alone (FSO & Economiesuisse, 2010). These amounts can be compared to the CHF 4.1 billion spent by the Confederation and higher education institutions on R&D expenditure in Switzerland. In 2012, the Swiss pharmaceutical industry invested CHF 3.8 billion in R&D, or 30 % of all R&D private expenditure in Switzerland, while the Confederation and the higher education institutions spent 5.4 billion CHF (FSO, 2014).

12 In 2001, 77 % of persons asked in the Eurobarometer survey in Switzerland agreed with the statement: “Even if it does not bring immediate benefits, scientific research that advances knowledge is necessary and should be supported by the government” (Crettaz von Roten et al., 2003). At the same time, the most widespread expectation is that scientific research *in general* should result in combating diseases (EC, 2001).

## 1.2 Approach

The SSIC set up a cross-disciplinary working group. At regular intervals, the group and the Council shared their considerations and views during plenary sessions. The results of these debates, which are the subject of this report, are also based on various external studies and discussions with partner institutions.

Firstly, the Council commissioned two studies into the meaning of biomedicine and biomedical research. The first (Strasser, 2014) traces the development of biomedicine as a new epistemological category from the beginning of the 20<sup>th</sup> century up to the present day. The second (Benninghoff et al., 2014) explores the contemporary landscape of Swiss public biomedical research in terms of the institutional players and individual researchers working in it. These studies, which look at the field of biomedicine from complementary perspectives, were published by the SSIC simultaneously, under the responsibility of their respective authors. A project by the Swiss Academies of Arts and Sciences into the concepts of a “sustainable health system” and “sustainable medicine” (Swiss Academies of Arts and Sciences, 2012; SAMS, 2012) provided a further basis for this report. Finally, the SSIC initiated a study identifying the players in biomedical research and assessing the debate on the quality of clinical research in Switzerland (Steiger, 2015).

Secondly, meetings have served to atune developments in the Council’s reflections with the concerns of the State Secretariat for Education, Research and Innovation (SERI), particularly regarding the close links between training and biomedical research. The interface between the project and public health issues has been explored with the Federal Office of Public Health (FOPH).<sup>13</sup> Discussions with experts from the pharmaceutical industry have investigated the issue of public and private research partnerships. Finally, the Council’s proposals and recommendations were discussed with experts during a dedicated session held in Bern on 16 September 2014.

## 1.3 Structure

In the following chapter (Chapter 2), the Council offers an open definition of the notion of “biomedicine” with regard to the diversity of actors in the field. It lists the main contributions of biomedical research to knowledge, society and the economy (Chapter 3) before focusing (Chapter 4) on three challenges raised by developments in biomedicine: the “sustainability” of the health system, the “scientification” of research and medical training and the relationship between disciplines and, finally, the “applicability” of research.

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<sup>13</sup> The main tasks coordinated by the FOPH in the field of biomedicine include the implementation of the Federal Act on Research involving Human Beings (SR 810.30), the Master Plan or measures by the federal government to promote biomedical research and technology (Federal Council, Bern, 18.12.2013, accessible at: [www.bag.admin.ch/themen/medizin/14583/index.html?lang=fr](http://www.bag.admin.ch/themen/medizin/14583/index.html?lang=fr)) and the work of the “Future of medical training” Platform (cf. [www.bag.admin.ch/themen/berufe/11724/?lang=fr](http://www.bag.admin.ch/themen/berufe/11724/?lang=fr)), with which the SSIC is associated.

## 2 What is biomedicine?

### 2.1 Biomedicine

The notion of biomedicine conveys, using a linguistic shortcut, the growing influence throughout the 20<sup>th</sup> century of the natural sciences on the development of medicine. An example serves to symbolise this marriage of practices: the Nobel Prize “in Physiology or Medicine” has, for several decades, been awarded to researchers in biology or fundamental chemistry, with the same candidates often being nominated for a Nobel Prize in both chemistry and medicine. A notable exception was when the prize was awarded to doctors Barry Marshall and Robin Warren in October 2005, for identifying the *Helicobacter pylori* bacterium as the cause of stomach ulcers. Over the past 20 years, only two other recipients have had a medical degree, although they were not clinicians: Stanley B. Prusiner for the discovery of prions in 1997 and Harald zur Hausen for the discovery of papilloma viruses in 2008.

In Switzerland, researchers from many disciplines now define their research as “biomedical” to indicate that their activities have an actual or potential medical application (Benninghoff et al., 2014). The “biomedical” label marks either the social relevance of basic research or, more rarely, the scientific basis of clinical research. However, there is no consensus on what the term “biomedicine” covers, and the fact that there is no single definition does not appear to be problematic in the eyes of the players.<sup>14</sup> Rather, it seems that a certain terminological plasticity is maintained in order to provide the foundation for a common language which allows disciplinary and institutional barriers to be overcome.

Biomedical research thus covers a broad disciplinary spectrum in which both medicine and much of biology play a key yet non-exclusive role. It may include both basic (physics, chemistry, biology) and applied research (clinical research, epidemiology, pharmacology, medical technology). It is not easy to accurately locate recent disciplines such as immunology and bioinformatics on the gradient leading from basic to applied research. In view of this range of natural and technical disciplines, social sciences and human-

ities play the modest but increasingly important role of interlocutor (Swiss Academies of Arts and Sciences, 2012).<sup>15</sup> Just as there is epistemic diversity in the domain of biomedical research, there is also a profusion of places in which it takes place: public and private hospitals, university and non-university institutions, pharmaceutical and biotechnology companies or those specialising in medical technology (cf. Box 1; Steiger, 2015).

The SSIC sees “biomedicine” as an open notion which can only be defined retrospectively, given the unpredictability of results and, more importantly, of the applications of a research project. As a result of its indefinite nature, some assert that biomedicine does not exist as a disciplinary research practice, notably because of the disparity between the stated objectives and those actually pursued by researchers (cf. Benninghoff et al., 2014).

14 For example, the SAMS does not see clinical research as forming part of bio-medicine, while the SNSF presents it as belonging to this field in its official documents (Benninghoff et al., 2014).

15 According to the SAMS, the *medical humanities* do not yet constitute a well-established field and primarily involve the training of doctors and carers, with little research conducted ([www.akademien-schweiz.ch/fr/index/Schwerpunktthemen/Gesundheitssystem-im-Wandel/Medical-Humanities.html](http://www.akademien-schweiz.ch/fr/index/Schwerpunktthemen/Gesundheitssystem-im-Wandel/Medical-Humanities.html), consulted 04.04.2014).

## Box 1

### Biomedical landscape in Switzerland

The scientific community is primarily seen as being international. However, thanks to their institutional links, biomedical researchers are anchored in a defined geographical and political place – with the exception of research in multinational companies. The main institutional players who make up the biomedical research landscape in Switzerland are thus:

- *Academic structures.* The last decade has seen much change and restructuring, including the creation of the Faculty of Biology and Medicine in Lausanne in 2003, following the transfer of the rest of the Natural Sciences Faculty to the EPFL. A closer integration process between the University of Lausanne and the Centre hospitalier universitaire vaudois (CHUV) was initiated with the Swiss Cancer Center Lausanne (SCCL) project. In recent years the ETH Domain has set up structures with a biomedical focus, for example the Faculty of Life Sciences at the EPFL in 2004 and the Faculty of Health Sciences at the ETHZ in 2012 (Leresche et al., 2012). Finally, the Università della Svizzera italiana (USI) intends to create a new Faculty of Biomedical Sciences offering master of medicine degrees by 2017.<sup>16</sup> Some universities of applied sciences have devoted structures to health or biomedical technologies, for example the School of Life Sciences at the University of Applied Sciences and Arts Northwestern Switzerland (FHNW), founded in 2006.
- *Non-university research institutes.* Some of these institutes are private, such as the Friedrich Miescher Institute (FMI), funded by the Novartis Foundation or Robert Mathys Foundation (RMS). Many are financed in part by the local canton or commune and by the Confederation under Article 15 RIPA: Institute for Research in Biomedicine (IRB), Biotechnologie Institut Thurgau (BITg), Institute for Oncology Research (IOR), Institut de recherche en ophtalmologie (IRO), Swiss Vaccine Research Institute (SVRI), Swiss Tropical and Public Health Institute (SwissTPH), Swiss Institute for Bioinformatics (SIB), Swiss Institute of Allergy and Asthma Research (SIAF), Swiss Paraplegic Research (SPF),

Swiss Group for Clinical Cancer Research (SAKK), Swiss Center for Applied Human Toxicology (SCAHT). Some of these institutes might soon become university structures (IRB, IOR). Moreover, the Confederation intends to help fund the Swiss Clinical Trial Organisation (SCTO)<sup>17</sup> in accordance with Article 15 RIPA for the period 2017–2020 (Federal Council, 2013).

- *Hospitals as centres of research.* In many respects, especially in terms of publication activity in scientific journals, it is no longer possible to distinguish between university hospital and medical faculty, as the two institutions often overlap.<sup>18</sup> In some cases, basic research laboratories are even set up within hospitals themselves. At the same time, the difficulty of combining research and training in an environment where the primary purpose remains patients care makes the hospital environment unique. Besides the five university hospitals in Switzerland, many cantonal hospitals have increased their clinical research efforts, especially St. Gallen, Lucerne, Ticino and Aarau, although the extent of these activities is still modest. Some private clinics have established clinical research programmes in order to attract the best medical doctors and ensure long-term quality of care. During the period 2008–2012, the SNSF launched a competitive call for projects and supported the establishment of six clinical research centres of competence (Clinical Trial Units) in university hospitals and in the St. Gallen cantonal hospital. These research infrastructures are now funded primarily by hospitals and medical faculties, whilst the SNSF assumes some service charges linked to projects.<sup>19</sup>
- *Research networks.* One striking phenomenon is the upturn of research networks, some of which might form lasting institutions when there is a wish to create a research infrastructure (SIB, SCTO, cohort studies may also be viewed as research networks). Others are designed as more transient structures when intended as a research capability, such as SystemsX.ch, the National Centres of Competence in Research (NCCRs)<sup>20</sup> or the Cooperation and Innovation Project (CIP) SwissTransMed<sup>21</sup>. The SNSF's Sinergia programme is popular with biomedical researchers.<sup>22</sup> There are currently proposals for new national initiatives such as *Personalised Health*, at the interface between systems biology and personalised medicine.

– *Private companies* (pharmaceutical, biotech and technical-medical). These are the most important players by volume of spending but the least well known in the Swiss biomedical landscape. Roche and Novartis alone hold a 10 percent share of the global drug market. The other members of the pharmaceutical industry based in Switzerland are much smaller. In addition, 80 percent of the 146 companies listed by the Swiss Biotech Association as “dedicated biotech companies” are active in the human health sector. Switzerland has another 386 medical technology manufacturers (medtech companies) of various sizes. Even areas on the periphery of the health sector, such as cosmetics and nutrition, are playing an increasingly active role in biomedical R&D.

16 [www.press.usi.ch/comunicati-stampa/comunicato-stampa.htm?id=1075](http://www.press.usi.ch/comunicati-stampa/comunicato-stampa.htm?id=1075).

17 In 2009, university and cantonal hospitals promoting the Clinical Trial Units (CTU), the Collège des Doyens des facultés de médecine and the SAMS formed the SCTO association, a cooperation network for clinical research in Switzerland. The association also acts as the Swiss coordinator for participation in the European Clinical Research Infrastructures Network (ECRIN).

18 For an explanation of the institutional relationship between hospitals and faculties, see Chap. 4.2.3.

19 Under the Biomedicine Master Plan, a CTU in principle functions like a university Clinical Research Organisation (CRO) (Federal Council, 2013, p. 100), offering support in planning and conducting clinical studies and in postgraduate training.

20 Of the 35 NCCRs completed or ongoing in 2014, 11 (Chemical Biology, CO-ME, Genetics, Kidney.CH, Molecular Oncology, Molecular Systems Engineering, Neuro, RNA&Disease, Structural Biology, SYNAPSY et TransCure) have a clearly biomedical focus, while five others (Affective Sciences, SESAM, BISRespMat, MUST, Nanoscale Sciences) have a partial link to this field.

21 For the period 2013–2016, the SwissTransMed CIP is allocating CHF 7 mio. to those cantonal universities wishing to form biomedical research networks with the ETH Domain.

22 Since the creation of the instrument in 2008, 48 % of applications for Sinergia funding are in the field of biology or medicine ([www.snf.ch/fr/encouragement/programmes/sinergia/Pages/default.aspx](http://www.snf.ch/fr/encouragement/programmes/sinergia/Pages/default.aspx)). The P3 database contains 203 accepted Sinergia programmes, of which 80 (39 %) can be clearly placed in the biomedical field (research from 02.04.2014).

## 2.2 Related notions

When clarifying the notion of “biomedicine”, attention should be paid to the “related notions”, that is to say the categories involved in the notion, which themselves cannot always be clearly defined.

The notion of *life sciences* primarily involves biology and related disciplines, but it has come to span an ever wider area, and now encompasses the entire field of biomedicine and other areas of application such as agriculture and biofuels. Unlike the term “biomedicine”, the expression does not suggest any intention to capitalise on knowledge or on any particular technology. In Switzerland it is mainly used by the private sector, in preference to more explicit terms such as “biotechnology” or “genetic engineering”.

Medical research or *clinical research* investigates human health and disease from the point of view of causes, detection, prevention and treatment. Research which focuses on causes and pathological mechanisms may take place in a laboratory, whilst research into diagnostic, preventive or therapeutic methods most often requires the direct participation of patients. Patient-centered clinical research includes the four clinical trial phases to test the introduction of new medicines, treatments or medical instruments, as well as epidemiological approaches such as cohort studies. Furthermore, a distinction should be made between clinical research and research into health services and effectiveness (outcomes), which looks at the application of health services, their quality and impact.

A special feature of the term “transversal research” or “*translational research*” is that it highlights the crucial stage at which advances in basic science are introduced into clinical research and the results of these studies are in turn relayed to laboratory researchers. It should be noted that there are a number of obstacles at the interface between the preclinical and clinical phases: preclinical trials may fail to identify a major risk for humans, may predict benefits which do not subsequently materialise or may forecast non-existent risks for humans (Dresser, 2009; Perrin, 2014). Because pathological models are not perfect, the translational process is often more iterative and bidirectional than linear (Marincola, 2003; Aguilar & Aguilar-Cordova, 2003). Inherently transdisciplinary, this

research is not a separate discipline, but rather a deliberate practice which aims to overcome barriers to the transfer of knowledge from one type of research to another. Some authors see translational research as a label (like “biomedical”), a reform movement in biomedicine or a buzzword (Bensaude-Vincent, 2014, Vignola-Gagné, 2014).

*Personalised medicine*, sometimes referred to as “precision medicine”, involves both research and medical practice, and seeks to view each patient as a biologically unique individual. Personalised medicine is a legacy of the decoding of the genome since the turn of the millenium. It still almost exclusively focuses on the influence of genes, although other individual characteristics can in principle be considered, such as microbial flora and physiological or environmental factors. Many of the current diagnostic tools are based on information from a few genes, used to classify patients and predict the appropriate drug or dosage for them (pharmacogenomics).

## 3 Achievements

### 3.1 Scientific knowledge

Although it may not be possible to define biomedicine in a strict sense, it may be understood as the result of an epistemic rapprochement occurring in the early 20<sup>th</sup> century between the study of the functioning of “normal” life and that of pathological processes. When seen as a biological species, humans become “accessible” to various natural disciplines, according to whether the level of analysis chosen is systemic, cellular, molecular or atomic. Even human psychology is understood to be the product of hundreds of thousands of years of evolution.

Our understanding of human beings as biological entities influences the way human research is carried out (Strasser, 2014). Firstly, there is the systematic use of a small number of living species as research models. A second feature is the almost universal focus on all forms of information with genetic character. The discovery of DNA as the physical medium of heredity has completed the synthesis between molecular biology and evolutionary theory. DNA’s linear character and chemical stability makes it easy to develop analytical and manipulation methods, with the result that the price of decoding a genome has dropped to a level that was inconceivable a short while ago. Finally, the semantic relationship between sickness and health has narrowed to the point that the notion of “disease” has now been replaced by that of “pathological risk”. Initially limited to statistical studies of human populations, this risk is now seen as applying to individuals, including those who consider themselves to be in good health (Strasser, 2014).

### 3.2 Life expectancy

Unlike improvements in health, which cannot be measured retrospectively because of their subjective nature,<sup>23</sup> life expectancy is more directly observable thanks to more than a hundred years’ of data available in industrialised countries.

According to the Federal Statistical Office (FSO), in 1880 the life expectancy of the Swiss population at birth was 41 years for men and 43 years for women.<sup>24</sup> High infant mortality had a strong impact on these figures: young adults could expect to live about sixty years. Today, average life expectancy at birth is 81 years for men and 85 years for women, and that for young adults is only slightly higher.<sup>25</sup> Similar trends have been observed in all industrialised countries: a very sharp drop in infant mortality in the first half of the 20<sup>th</sup> century, followed since the mid-1970s by a decline in mortality among the elderly, which still continues today (Seematter-Bagnoud & Paccaud, 2008). Admittedly, this development is due in large part to higher living standards and its corollaries, such as improvements in hygiene and nutrition. However, biomedical research has made a substantial contribution to the rise in life expectancy. The advent of vaccines and antibiotics is credited with having had a major impact, as did – though to a lesser extent – the development of emergency medicine and obstetrics (Cutler et al., 2006).

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23 In particular because of changing expectations with regard to personal health. For a definition of health, see also SAMS, 2012.

24 Cumulative observation period 1876–1880.

25 FSO figures for 2012.

### 3.3 Consequences for innovation

The healthcare market is a cornerstone of the Swiss economy. The health system employs nearly 13 percent of the workforce.<sup>26</sup> Between 1995 and 2005, the annual increase in the number of jobs in this sector was significantly higher (2.5%) than for the economy as a whole (0.4%) (FSO, 2007). Growth was most sustained in the production and trade in health goods, at an average annual rate of 3.2 percent. These results demonstrate the success of the pharmaceutical and technical-medical industry, in particular in exports. For 2011, the overall turnover of the health sector in Switzerland rose to 60 billion francs on the domestic market, while exports were worth 70 billion francs, of which 60 billion francs were accounted for by the pharmaceutical industry alone (Economiesuisse, 2011).

Whereas Roche and Novartis have filed a large number of patents and expanded their workforce over the past decade, small and medium-sized enterprises (SMEs) in medtech and biotech industries are growing in number rather than size (Countess & Zinkl, 2013). Only a quarter of listed biotech companies in 2012 already existed before 2000; three of them were founded before 1980. Most have fewer than nine employees, and only three companies (Actelion, Debiopharm and Crucell) have more than 250 (SBA, 2013). Biomedical innovation is now defined primarily in terms of patent applications, and this is financially unattractive for SMEs (see SSTC, 2013). In fact, the role of small businesses in the ecosystem of biomedical research is generally underestimated.

Despite its success, the pharmaceutical industry is facing increasingly high R&D costs in developing new drugs for the market. There is a considerable amount of drug development projects abandoned at a late stage in clinical trials, especially because of the risk of serious side-effects in a small number of patients. For this reason, efforts are being made to replace the current economic model of blockbuster by a “personalised” and systemic approach to biomedical innovation:<sup>27</sup> by combining treatment and a diagnostic test, patients who are likely to respond favourably to treatment can be targeted. The potential of the so-called “personalised” approach is regularly highlighted by

experts, who predict that the health system could be radically transformed in this way (ESF, 2012) or who argue that the public should invest in large specifically dedicated funding programmes.<sup>28</sup> However, it is still too early to assess whether personalised medicine will effectively replace the current economic model.<sup>29</sup>

Nevertheless, it is already certain that patients will be offered more and more individualised genetic advice. The new genomic diagnostics market looks set to thrive in the Swiss system, in which individuals attach great importance to their health and which is already largely financed on a private basis. This novel form of medical consultation, which may go even as far as forgoing a medical doctor’s services, raises significant societal challenges.<sup>30</sup> From a legal point of view, for example, the “right not to know”, in principle granted to everyone, is automatically questioned for the relatives of an individual wishing to have his own genome sequenced. However, most people have difficulty understanding predictions presented as probabilities and even more deciding how to make use of them (McBride et al., 2010). What should be said to a healthy person who, according to the current state of knowledge, has a 20 percent risk of developing a catastrophic illness?

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26 FSO figures for 2008.

27 The systemic approach in the vocabulary of innovation involves designing and developing several complementary innovative solutions in parallel in order to take better account of the needs of the target audience.

28 Under the Swiss Personalised Health initiative (see p. 18), several institutions, in particular the SAMS and the ETH Board, are drawing attention to the issue of standardisation and of the quality control of medical data in order to facilitate the sharing of such data.

29 A small number of significant advances can be attributed to the personalised approach, in particular in certain cancer treatments.

30 The current revision of the Federal Act on Human Genetic Testing aims to limit the use of new genetic tests in the absence of a medical doctor’s approval.



## 4 Challenges

The growth of health economics and the sometimes idealised accounts of successes in biomedical research have encouraged a large number of stakeholders to become actively involved in the work of researchers; governments and administrators make it a political priority, patient organisations, private foundations and sponsors select and promote certain types of research over others (Strasser, 2014). The participatory opportunities provided by new communication technologies have even allowed some patients to become active in their own “research” (Rabeharisoa & Callon, 2002). Biomedical researchers have become the direct interlocutors of numerous instances and subject to pressures that are not always economic, such as wanting to respond to patients’ hopes.

Indeed, the SSIC notes the irreversible nature of the convergence between medical and natural sciences. However, economic and social expectations surrounding biomedicine have evolved faster than its actual success, so that scientists regularly need to call to mind – or even explain – the limits of their powers. The implications of biomedicine as a transdisciplinary field with multiple interfaces centre on three issues that require development: “sustainability”, “scientification” and “applicability”.

### 4.1 “Sustainability”

The sustainability problematic as applied to biomedicine can be viewed from at least two perspectives: the effects of biomedical research on the costs of the public health system on the one hand, and the possible lack of health care professionals on the other.

#### 4.1.1 Biomedical research and sustainability in medicine

In a 2007 study, the FSO projected that spending in the Swiss health system would increase by a factor of 2.2 to 2.4 by the year 2030 (Vuilleumier et al., 2007). The share of health spending could well rise to between 14.4 percent and 17.2 percent of GDP, compared with 11 percent today.<sup>31</sup> Contrary to what is generally supposed, such increases are not primarily a result of the aging population, but rather the cumulative effect of two mutually reinforcing factors: technological progress and a lowering of the pathological threshold.<sup>32</sup> Indeed, while some medical innovations lead to a reduction in the number of follow-up treatments, others cause the volume of care to expand (Bratan & Wydra, 2013). Empirical studies tend to conclude that, on balance, technological progress increases the volume of care rather than reducing it (Cutler & Huckman, 2003; Bodenheimer, 2005). Furthermore, the lowering of the pathological threshold, that is to say the change in both physicians’ and patients’ perception of what “deserves medical treatment”, is itself influenced by advances in scientific knowledge (Vuilleumier et al., 2007). As a result, the issue of sustainability in medicine can indeed be perceived as linked to the development of biomedical research.<sup>33</sup>

The SAMS defines “sustainable medicine” as a medicine capable of responding to the needs of the present without compromising future generations’ possibility of addressing their own needs (SAMS, 2012). The level of medicalisation necessary to ensure a quality of life

31 According to the WHO, health spending in the US already reached 17,2 % of GDP in 2011.

32 See Vuilleumier et al., 2007 on the minor role of demographic aging, in particular p. 8 and p. 17.

33 The SAMS identifies a number of additional problems independent of biomedical development, in particular false financial incentives resulting from the payment system for care providers and the differences in costing keys between the different areas of care provision (SAMS, 2012).

that is considered satisfactory depends essentially on personal expectations; these evolve from one generation to another and even during the course of an individual life. Therefore, the extent of the “health needs” that society is willing to accept must be defined in a political process of prioritisation and be based on principles of fairness and solidarity.

The research world’s contribution to the advent of such a system of “sustainable medicine” could be to develop research into health services and to place a new focus on factors that preserve health, which are much less understood today than pathological factors. The technical possibilities for monitoring physiological data would aid this approach (Gibbs, 2014) at the same time as raising issues regarding the use and security of personal data (Eckart et al., 2014). In order for the preventive approach to encompass more than a mere disclosure of new pre-pathological states, it should not be limited to physiological aspects but also involve redefining health and quality of life in their psychological and social dimensions.

#### **4.1.2 Sustainability of the medical training system**

As demands and needs grow, the number of new medical doctors trained in Switzerland is stagnating, not for a lack of candidates, but because of limited training capacity for the years of clinical formation. The Swiss Science and Technology Council has contributed to this debate by calling for increased capacity in Swiss medical faculties (SSTC, 2007); this capacity is currently being developed. Relative to its population and compared with other countries, Switzerland trains a substantial number of physicians (see Table 1, p. 30). At the same time, efforts are being made to delegate more medical tasks and responsibilities to other healthcare professionals according to the principle of subsidiarity.<sup>34</sup> Despite these efforts, the resource which is most limited and subject to most pressure is the working time of doctors. With the “economisation” of medical practice, which forces doctors to account for each moment not spent on patient care, one wonders how young doctors could still be motivated to engage in clinical research or even in interdisciplinary collaboration. However, as will be seen in the next section (4.2.1), the importance of clinical research in the training of doctors and beyond is a determining factor in the development of an “open” biomedical research.

## **4.2 “Scientification”**

Because it operates in the field of research and medical practice, biomedicine feeds the debate on the “scientification” of medicine, in terms of both its positively and negatively viewed aspects. The SSIC considers this challenge from three angles: the positioning of clinical research within biomedicine, the resulting structural effects on the development of transdisciplinarity and the organisation of university medicine in an international context.

### **4.2.1 Positioning of clinical research within biomedicine**

Since the gap between the natural and medical disciplines began to close, thereby leading to the “scientification” of medicine, comparisons have been made between the level of clinical research and that of basic science, using measurement tools more likely to meet the quality standards of the latter. The debate on the quality of clinical research peaked between the 1990s and early 2000s, when several institutional players became concerned and called for specific measures to promote clinical research (SSTC, 2002; SNSF, 2005). The debate has continued and is still topical as of today (cf. Box 2; Steiger, 2015).

While the natural and technical sciences enjoy immediate prestige, including in the scientific community itself, clinical medical research, by contrast, endures a lack of recognition; its contribution to the advancement of knowledge and treatment options is often considered less obvious or less “scientific” (Strasser, 2014). The primacy given to a linear, simplified model of the innovation process, in which clinical studies are merely supposed to standardise a scientific discovery made in the laboratory, reinforces the implicit depreciation. However, one must not forget the extent to which a clinician’s experience can contribute to advances in scientific knowledge.<sup>35</sup>

34 The draft Healthcare Occupations Act, modelled on the Medical Professions Act, aims in particular to increase the competency of care professionals.

35 For example, while the standard care for preterm babies was, until the late 1970s, to keep them in an incubator, Colombian doctor Prof. Edgar Rey Sanabria introduced a method of placing premature infants on their mothers’ chest, in part to alleviate resource shortages at his hospital. The method has become established, also in rich countries, and has helped to advance knowledge on the neurological and emotional development of infants in general (Feldman et al., 2002).

A caricatural and reductionist perception of the role of clinical research could prove damaging to the future of biomedicine itself, especially at a time when the latter should be opening up to other disciplines, such as the medical humanities. As H. I. Ralph notes in the journal *Science*, the issue goes far beyond the bounds of biomedicine. “Unless clinical, social, and environmental features that affect the outcomes of disease are also incorporated, the current approach may be carving a path to ‘depersonalised’ medicine, both in its science and its relevance to medical practice.” Indeed, personalised medicine as it is understood today is often equated to merely classifying patients based on a small number of technical indicators in order to meet the requirements of classical experimental research (Eckart et al., 2014). However, in the public view, this approach would be called technical rather than personal, and appeals less than the long-term holistic approach provided by general practice (Suske, 2014).

Despite good results (cf. Box 2), in Switzerland as in other countries clinical research still has a separate status, both in purpose and in context. For clinicians, launching clinical research projects involves administrative effort and little or no financial gain, while participating in a large study provides close to no scientific visibility as a large number of individuals share authorship for a single publication. For human subjects, participating in a clinical trial may mean exposing their health for altruistic reasons.<sup>36</sup>

University faculties, hospitals and the SNSF should therefore strive to free up more time for research and mentoring young clinicians.<sup>37</sup> Because pharmaceutical companies need to develop new markets, there has been a drop in the number of clinical studies carried out in recent years in Switzerland as well as in Europe generally.<sup>38</sup> The speed of the authorisation process also plays a role, especially in favour of countries such as Holland or New Zealand. However, if this decrease becomes more acute, it could eventually result in a loss of know-how and scientific reputation, or even in a reduction in the quality of medical care, for the correlation between the latter and the intensity of clinical research in a given country is well-known.

36 Healthy participants rather than patients are exposed to an actual risk. It must be remembered that any therapeutic act represents a risk, and many studies have shown the benefits to patients of participating in a clinical trial compared to receiving conventional treatment (Vist et al., 2009).

37 See on this issue the recommendations of the working group “Young academics for clinical research in Switzerland” (“Future of medical training” Platform, 2014).

38 According to the European Commission, there was a 25% decrease in applications for authorisation of clinical trials between 2007 and 2011; the Commission sees in this a reason to liberalise the current Directive 2001/20/EC (European Commission, 2012, p. 2). For its part, Swissmedic recorded a 25% drop (from 318 to 237) in the number of clinical drug trials reported between 2009 and 2012 (Swissmedic, 2012, p. 36; Swissmedic, 2013, p. 40).

## Box 2

### Debate on the quality of clinical research

Since at least the early 1990s, the quality of clinical research in Switzerland has been the subject of controversies that still continue today. For example, the Master Plan for Biomedical research and technology states that clinical research is of a high quality, while the working group of the “Future of medical training” Platform, looking at the issue of young academics in clinical research in Switzerland, holds an opposing view. By virtue of its unique object – human beings – and context (mainly hospitals), clinical research must meet more criteria than other types of scientific research.

First, as a scientific undertaking, clinical research must subscribe to the ideal standards which apply to all research: methodological rigour, reproducibility, originality... Essentially, these standards can only really be understood by a specialist in the field. The use of bibliometric indicators often gives an approximated idea of the quality of the research, especially for readers who do not have expertise in the discipline in question.<sup>39</sup> Success in securing competitive research funding is also viewed as indicative of the quality of the researchers. One particular problem arising in clinical research is that a large number of colleagues are required for the success of a multicentre study. Clinicians have little chance of boosting their academic career by including their name in a long list of co-authors, as it is virtually impossible for the evaluators to assess the actual contribution of each author.

As an undertaking involving research on humans, clinical research must also comply with formal and ethical criteria unknown in other scientific disciplines. Some of these criteria (good clinical practices) are formal conditions set in authorisation application procedures. Standardisation by means of these criteria is essential if the various professionals (e.g. doctors and nurses), internal and external partners (in the case of clinical research organisations), spread over multiple sites and occasionally several continents are to be able to collaborate on a clear basis. Ethical criteria such as transparency and researchers’ disinterest are key, especially when private industry sponsors clinical trials. Society and participants in clinical trials wish to see all clinical studies published in a transparent manner,

whilst researchers, sponsors and even scientific publishers have no direct interest in publishing negative results or unfinished studies (a problem known as “publication bias”). Finally, as a form of applied research, clinical research also aims to be “applicable” or useful beyond actual research circles. For this to be the case, it must not only be possible to reproduce and apply the research generally, but it should also be directed at the needs of the health system from the design phase onwards. Quantifying the number of bibliometric citations is of little use in the clinical context. New tools are needed to assess the dissemination of clinical research results, for example at the Clinical Guidelines level (Rosas et al., 2013).

It is understandable that different players hold different views on the issue of quality in clinical research. Clearly, managerial and organisational skills, although essential to the success of a clinical study, do not reflect the essence of what most experts consider to be “quality” in clinical research. The SSIC draws the following conclusions from the study which aims to clarify this issue (Steiger, 2015): Swiss clinical researchers are able to publish their research results in reputable scientific journals, and the rate at which their articles are cited by international centres of excellence remains constant or has even risen slightly. At the same time, Swiss researchers today publish three times more than a decade ago – which, however, does not mean that the number of research projects has increased by the same proportion.<sup>40</sup>

Despite these encouraging results, clinical research in Switzerland could still arguably be improved, for example in terms of the number (currently not known for Switzerland) of clinical trials which have never been published, the relatively high rate of requests rejected by the SNSF, and the frequently poor internal consistency and command of statistical tools found in applications submitted to the ethics commissions. However, one must remember that all these problems are also found in other European countries and the USA, and one should avoid comparing basic biomedical research to clinical research without considering the different contexts and criteria.

39 Initially, bibliometric indicators were developed with the aim of measuring the reputation of scientific reviews. Today they are most often used to provide *indirect* information on the quality of articles and even of their authors, by highlighting how the scientific community receives the evidence and the theories.

40 The number of scientific journals has increased, as has the propensity of Swiss researchers to collaborate with foreign partners.

#### 4.2.2 Measures in favour of transdisciplinarity

Researchers who consider themselves as players in the biomedical field retain a strong attachment to their disciplinary identity (Benninghoff et al., 2004). Consequently, biomedical research exists as translational and interdisciplinary research rather than as a discipline in itself.

Transdisciplinarity provides an opportunity to ask new questions, both in research and in innovation, but it also implies risk, especially for the careers of young researchers, who are often advised to start out and establish themselves in an area of expertise before venturing into such an undertaking. For example, transdisciplinarity involves working with partners from other disciplinary cultures, whose level and skills cannot be assessed with the usual accuracy. To make a dialogue possible, ideally in an informal context, a common language needs to be developed, which involves considerable intellectual effort. The search for competitive funding poses a particular challenge, as evaluators tend to judge those parts of an application which diverge most from their area of expertise as being too superficial. All these problems are well known; but in scientific practice, progress is modest and continues to be made on a classic disciplinary basis, i.e. individually.

However, new initiatives have opened up opportunities to promote transdisciplinary research. The MD-PhD curriculum set up by SAMS and the SNSF in 1992 has led to the emergence of a new type of doctor intended to serve as a bridge between cultures.<sup>41</sup> In 2007, a large number of these young doctors were involved in basic or translational research (Kühnle et al., 2009). Efforts are underway to involve clinical research to a greater extent in the MD-PhD curriculum.<sup>42</sup> Bridging (“passerelle”) programmes which enable holders of first degrees in engineering<sup>43</sup> or natural sciences<sup>44</sup> to progress to a master’s degree in medicine are also being developed.

In addition, some faculties have reorganised in such a way that medicine is more closely linked to the natural or technical sciences (p. 18). The most notable organisational innovation is undoubtedly the creation of the Faculty of Biology and Medicine at the University of Lausanne, although it has not necessarily led to a change in culture, and the biology and medicine centres in fact remain quite distant from each other. At

the same time, faculties and research institutes in the ETH Domain have begun to build new structures and create new ties with medical faculties, so that their co-operation, which initially focused on research, now aims to include medical training (ETH Board, 2010; Aebischer et al., 2011; Federal Council, 2013<sup>45</sup>). An example of this is the launch of the SwissTransMed research networks,<sup>46</sup> which must include at least one university hospital or medical faculty as well as one ETH Domain institution.<sup>47</sup>

#### 4.2.3 Organisation of university medicine

In Switzerland, governance models and institutional relations between hospitals and medical faculties are the subject of regular debate. Indeed, medical training, from the first years of study, cannot any more be conceived in isolation from the practical skills fostered in clinical and university hospital centres (SSTC, 2006). Originally conceived as structures intended to introduce students to the most common ailments, these clinics tend to concentrate services in the most advanced medical practices and specialities, at the risk of putting training and research activities in second place.

41 Switzerland was the first country in Europe to introduce this programme, which was developed in the USA in the 1960’s.

42 See the recommendations of the “Young academics for clinical research in Switzerland” working group of the “Future of medical training” platform.

43 See the Biomedicine Master Plan (Federal Council, 2013, p. 109).

44 See in particular the Master in Medicine project in Ticino, as described in the cantonal dispatch.

45 Biomedicine Master Plan, p. 103: “Under the ETH Medical Strategy, close collaboration at institutional and subject level in the field of teaching and research between the ETH Domain, the medical faculties of the universities of Bern, Lausanne, Geneva, Zurich and Basel as well as university hospitals is planned (development of medical schools, which systematically combine engineering sciences, medicine and biology)” (Federal Council, 2013).

46 “For the purpose of this proposal, a platform is defined as a collaborative network of researchers from different institutions with access to infrastructure and expertise required to address the clinical problem described in the proposal and to develop and evaluate appropriate interventions” (cf. [www.swisstransmed.ch/?page\\_id=204](http://www.swisstransmed.ch/?page_id=204), consulted 31.03.2014).

47 By comparison, the universities of applied sciences and cantonal universities without a complete medical faculty such as the University of Fribourg cannot be full members of a SwissTransMed network (cf. [www.swisstransmed.ch/?page\\_id=231](http://www.swisstransmed.ch/?page_id=231), consulted 31.03.2014).

The generic term “Academic Medical Center” (AMC) refers to an academic medical institution and its associated clinical establishment(s). In itself, the name AMC does not specify the type of relationship between university and clinic, which can be organised according to various models (see Table 1, p. 30). In the first model, known as “integrative”, decision-making powers lie with a single entity linking the clinic and the faculty. In this configuration, which is encountered in particular in the Netherlands and in some American AMCs, one entity alone has a three-fold mission. In the second “cooperative” model, which is widespread particularly in Switzerland and Germany, the university clinic is independent of the university. Close links between the two institutions are assured by the faculty dean’s position on the management board of the clinic, and most senior positions involve both direction of a clinical unit and tenure of a university chair. The institutional autonomy is most advanced in Austria, where medical faculties have been transformed into medical universities. In the USA model, many possibilities coexist: medical schools may be independent (14%) or associated with a larger academic institution (86%); likewise, their links with teaching hospitals may be integrative (Johns Hopkins, Yale) or cooperative (Harvard, Stanford) (Bunton et al., 2013). The study commissioned by the SSIC confirmed that for nearly all the experts consulted, the USA remain the standard for clinical and biomedical research in general (Steiger, 2015). Even in medical training, reforms introduced in Swiss medical faculties are based on the North American model (SSTC, 2011, pp.16–18). A comparison of Swiss and American training systems (Box 3) reveals that the duration of studies is roughly similar with a minimum of 11 to 12 years of training, although the number of weekly hours is lower in Switzerland because of national labour laws.<sup>48</sup> Selection at entry to studies is much more elaborated in the USA than in Switzerland. The quality of training and research is less homogeneous in the USA, where there are two types of medical school: research-intensive and community-based.<sup>49</sup> Similarly, there are more varied types of institutional relationship between the academic and hospital environment in the USA, even though many medical schools enjoy greater autonomy from their university than Swiss medical faculties, in which the position of dean is traditionally in-

vested with few decision-making powers. The average number of students is slightly higher in a Swiss faculty than in an American medical school. Both systems rely heavily on the supply of doctors trained abroad, who join the system at postgraduate training level: 35 percent of physicians doing a residency in the USA and up to half of junior doctors in Switzerland graduated abroad. Clinical research in the United States receives a larger share of public funding than in Switzerland. In addition, the country has both public (NIH Clinical Centers<sup>50</sup>) and private (Johns Hopkins Medicine) research centres which are considerably larger than those in Switzerland. International comparisons suggest that a wide range of organisational models can help to reconcile academic requirements with hospital practice, although no one solution can resolve once and for all the tensions inherent in the threefold mission to provide training, research and medical services.

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48 SR 822.11.

49 In 2011, the average budget of a research-intensive medical school was USD 1.5 billion compared with 120 USD million for a community-based medical school.

50 The NIH Clinical Center in Bethesda (MD) runs a particularly high number of clinical studies involving a special risk for patients (first-in-human); it receives 10,000 new participants in clinical trials each year.

### Box 3

## The American “medical schools” model

At international level, the term “medical school” applies to all university medical institutions, including the Swiss medical faculties. In the USA, the term refers to a particular type of academic institution training students at the level of professional master. In comparison, medical schools in the UK train students at the bachelor and master levels. In Switzerland, the Federal Council has proposed establishing medical schools which would involve a closer cooperative relationship between medical faculties, university clinics and faculties at the federal institutes of technology.

In order to gain a place at one of the 141 medical schools accredited by the Liaison Committee on Medical Education (LCME), students must be in possession of a bachelor degree in any major discipline. The USA bachelor degree lasts four years; the first two years of study are fairly general, involving courses in natural sciences, social sciences and humanities. To gain admission to medical school, candidates must submit a written application and are then interviewed. Most schools require candidates to have a bachelor degree involving a minimum of one year of courses in the following branches: biology, inorganic chemistry, organic chemistry, English and mathematics. Students need to obtain a good bachelor degree to be considered for a place at medical school. A further selection criterion is the result of the *Medical College Admission Test (MCAT)*; a reformed version of this examination, which gives more weight to social and human sciences, shall be introduced in 2015.

Medical school training lasts four years and leads to the title of medical doctor (MD). The first two years are mostly devoted to general biomedical branches, and the final two to a series of clinical rotations or “clerkships”. The average cost of a year of medical school is USD 31,000 for students at a public school in their state of residence. Private medical schools cost, on average, USD 48,000 per year. However, the main source of income is revenue from care services provided by members of the school (37% of the total budget) and federal research funding, far ahead of study fees (3–4% of the budget). 87 percent of medical students run up substantial debt to obtain their MD.

Medical training continues with a residency in a teaching hospital, of which there are more than 1,000. Just over 9,000 programmes for a total of 115,000 residencies were recorded in 2012–2013. They last from three to six years, sometimes more, depending on the speciality. In some cases, specialisation is followed by a sub-specialisation or “fellowship”. The first year of residency is often referred to as internship, and it is during this stage that the third and final step of the *United States Medical Licensing Examination (USMLE)* takes place. A licence to practise medicine is awarded by the individual states, based on the results obtained in the federal exam.

Level	Stage	Duration
<i>Pre-med education</i>	<i>Bachelor</i> (in any major discipline)	4 years
<i>Undergraduate medical education</i>	<i>Professional Master</i> ( <i>Medical Doctor</i> or MD)	4 years
<i>Graduate medical education</i>	<i>Residency</i> (first year is known as <i>Internship</i> )	3 to 5 years, possibly longer
<i>Graduate medical education (optional)</i>	<i>Fellowship</i>	variable

### Stages in medical training in the United States

## 4.2.3 Organisation of university medicine

	Switzerland (pop. in 2013: 8.0 mio.)	Germany (pop. 80.8 mio.)	Austria (pop. 8.5 mio.)	USA (pop. 313.8 mio.)
<b>Number of first-year study places</b>	1,600 <sup>51</sup> reserved for residents	11,000	1,350 (75 % reserved for residents)	20,000
<b>Number of medical degrees awarded</b>	769 (2014: 861)	10,000 <sup>52</sup>	1,650 <sup>57</sup>	18,000 <sup>59</sup> (21,000 projected for 2016)
<b>Number of candidates per study place</b>	3	5	8	2.4 <sup>60</sup>
<b>Number of training and research institutions</b>	5 complete and 2 partial medical faculties (Univ. of Fribourg and Univ. of Neuchâtel)	37 medical faculties	3 medical universities (and one private medical university <sup>58</sup> )	141 medical schools
<b>Form of relationship with rest of university</b>	Integration	Integration <sup>53</sup>	Cooperation	Cooperation <sup>61</sup> or integration
<b>Form of relationship with clinic or hospital</b>	Cooperation with university hospital centre	Cooperation (29 faculties) or integration (8 faculties) <sup>54</sup> with university clinic	Cooperation	Cooperation or integration with teaching hospital <sup>62</sup>
<b>Recent developments</b>	Projects for new faculties and increase in study capacity	Reform of federalism. <sup>55</sup> Introduction of diagnosis related groups retribution mode <sup>56</sup>	Separation from original universities with 2002 law on universities	Ongoing effort to increase capacity by 30 % in 15 years

Table 1 Organisation of AMCs in different national systems

51 This number goes down substantially from the second year onwards as the universities of Lausanne and Geneva run a selection process at the end rather than the beginning of the first year. [www.swissuniversities.ch/de/services/anmeldung-zum-medizinstudium/statistiken/aufnahmekapazitaeten-20152016/](http://www.swissuniversities.ch/de/services/anmeldung-zum-medizinstudium/statistiken/aufnahmekapazitaeten-20152016/).

52 Medizinischer Fakultätentag 2013.

53 Except in Hanover, where a *Medizinische Hochschule* (medical university) has been established.

54 In Mainz and a few other sites, the university hospital has been completely encompassed by the university (model known as double integration).

55 Under the federal reforms of 2006/7, the Länder were given sole responsibility for funding the construction of universities. As a result, there is less renewal of infrastructures. Since the reform, the *Wissenschaftsrat* has been responsible for deciding on research infrastructure funding which is judged to be of strategic importance.

56 Many deficitary university hospitals consider that the German system of Diagnosis Related Groups does not sufficiently recognise the exceptional nature of the cases of last resort re-

ferred to them from other hospitals and organisational challenges arising from providing training, research and care in one institution.

57 This number also includes degrees in dentistry for the year 2011/2012 (STATISTIK AUSTRIA, Hochschulstatistik. Compiled on 07.08.2013).

58 Paracelsus Medizinische Privatuniversität (without *numerus clausus*).

59 Bunton et al., 2013.

60 It should however be noted that medical school candidates are already selected for a first time when they begin their bachelor degree course. Moreover, preparing an application involves considerable effort.

61 14 % of medical schools are independent of the broader university system.

62 116 integrated academic medical center hospitals and 138 independent academic medical center hospitals are members of the Council of Teaching Hospitals and Health Systems.



## 4.3 “Applicability”

The disparity between therapeutic advances and the expectations of patients and society may create a certain disenchantment regarding biomedical research, which may appear inefficient. There are three main reasons for questioning the scope of such a judgement regarding the alleged inapplicability of research. Firstly, advances in basic knowledge are themselves of great value. Secondly, biology and other natural sciences have proven beneficial in many practical areas, some of which also have significant implications for human health; species conservation, agriculture or biofuels come to mind. Thirdly, the scientific process does not set out to verify truths but to disprove hypotheses; it is based on the possibility that any research project could fail and any conclusion be called into question.

### 4.3.1 Reproducibility

Whereas researchers emphasise the importance of their activities by promising a potential therapeutic application, the scientific community is reflecting about the effectiveness of translational and clinical research. For example, in 2014, the journal *The Lancet* addressed this issue in a lead article with the following opening: “Of 1,575 reports about cancer prognostic markers published in 2005, 1,509 (96%) detailed at least one significant prognostic variable. However, few identified biomarkers have been confirmed by subsequent research and few have entered routine clinical practice. This pattern – initially promising findings not leading to improvements in health care – has been recorded across biomedical research” (Macleod, 2014). Various factors inhibit the translational dynamics of research, the first being a lack of reproducibility.

In biology and medicine, experiments and results are more difficult to replicate than in chemistry or physics, due to the inherent complexity of living organisms. Poor mastery of statistical instruments by biomedical researchers has been cited as a major reason why empirical results are misinterpreted (Ioannidis, 2005; Nuzzo, 2014). Moreover, a series of unsuccessful replications of academic publications by pharmaceutical companies has fed the debate on the reproducibility

of biomedical research.<sup>63</sup> In addition to this phenomenon comes the well-known problem of “publication bias”, which affects all types of experimental research, particularly those clinical trials whose outcome contradicts the expectations of those conducting or funding the trials (Riveros et al., 2013). Although registers of clinical trials have been set up by national and supranational authorities, publication bias is not on the decline: it actually seems to be becoming more widespread (Fanelli, 2012). Because the scientific literature gives a false representation of the reality of trials, new research is designed based on shaky foundations, while approaches doomed to failure may be replicated unnecessarily.

### 4.3.2 Productivity of pharmaceutical research

Academic and private research mainly focuses on drug therapies, even though such research priorities may not match the expectations of patients and physicians.<sup>64</sup> However, the number of innovative chemical compounds (new molecular entities) accepted by regulatory bodies is rising at a slower rate than the R&D costs of the pharmaceutical industry (Light & Lexchin, 2012; Juliano, 2013).

The dominant R&D model in pharmaceutical research is known as “rational drug design”. First, the complexity of the human body is reduced to a minimum, the assumption being that it can be recreated by means of technical artifices once the target molecule has been identified (Folkers, 2011). However, it turns out that a majority of noncommunicable diseases rely on a multifactorial genetic basis, and that the latter is counterbalanced by the crucial influence of the environmental context. For these diseases, the hope of developing a single molecule or magic bullet able to solve problems without complications is fairly illusory. Moreover, the pitfalls of the reductionist approach tend to become manifest only when a drug is tested over larger populations, or even after its release.

63 In particular, Bayer in 2011 and Amgen in 2012 (Wadman, 2013).

64 For example, patients and doctors would prefer to put the focus on research into rehabilitation, physical exercise and psychological care (Chalmers et al., 2014).

Rational drug design, although becoming ever more sophisticated, is not necessarily proving to be more effective than the “serendipities” that led to the discovery of the first medicines (Folkers, 2011). The principle of personalised medicine is therefore the logical response by the pharmaceutical industry to these difficulties; whether this new approach will be able to bring new medicines to a significant number of patients is still unanswered; it could also lead to redefining each patient as the carrier of a rare or orphan disease.

### 4.3.3 Creativity

In addition to methodological rigour and suitability of research models and processes, scientific advances rely on a small number of contributions of a disruptive nature, which may occur through either theories or empirical discoveries, new research methods or measuring instruments (Heinze, 2013). In the fields of human genetics and nanotechnology, a case study found that highly creative research groups flourish under the following organisational conditions (Heinze et al., 2009): the average group comprised six to eight researchers, enabling the direct participation of the principal investigator, institutional funding was generous and there was an easy access to expertise and infrastructure both within the institution and via external networks. Repeated assessments and a high dose of project funding were an obstacle to creativity. In terms of personal traits, creative individuals tend to show a high tolerance for risk, contradiction and uncertainty.

Aware of the trends jeopardising risk-taking, and in particular the reduction in basic institutional funding, the NIH launched an initiative to promote innovative biomedical research in 2004.<sup>65</sup> It would be interesting to investigate whether private foundations dedicated to or interested in the biomedical field could contribute to strive in a similar direction, even though the role of these foundations is far less important in Switzerland than in the United States.<sup>66</sup> On the other hand, it seems appropriate to consider introducing “high risk” research funding measures in order to counter the growing effects of mainstreaming (SNSF, 2010, p. 26). The SSIC envisages such measures as being aimed at a small number of radically new types of project. This would include requests for which prelim-

inary data, required for conventional project funding, are still lacking. Scientists who are already well established in their field could also take advantage of this in order to venture into a new research discipline.

In principle, support for the transition from basic to applied research is already being provided, both by the SNSF in its “basic research oriented towards application” category and by the CTI, in its R&D projects “without implementation partner”.<sup>67</sup> However, in the case of a project with therapeutic aim, the current funding situation does not necessarily meet the actual requirements in terms of infrastructure, time and venture capital. And although business creation is quite dynamic in Switzerland, particularly in the biomedical field, it appears that a majority of start-ups survive rather than thrive. For some analysts, this is explained by the fact that the overall culture does not allow for mistakes (Sieber, 2009).

The problems described in this chapter, generated by the massification and “economisation” of science, can be seen most clearly in the biomedical field due to the dual nature of the scientific results, which often translate both into advances in basic knowledge and at the same time into patented medical applications (SSTC, 2013). Ultimately, these phenomena push investigators towards a less rigorous, thus less applicable, kind of research, which is not strongly innovative and mainly disciplinary – rather than translational or transdisciplinary.

65 NIH High-Risk-High-Return programme (<https://commonfund.nih.gov/highrisk/index>).

66 For example, the funding model at the Howard Hughes Medical Institutes, which supports researchers rather than research projects.

67 RIPA Art. 19 para. 3: “The Confederation may fund feasibility studies, prototypes and pilot installations also without an implementation partner if [...] they have significant innovation potential.”

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# Abbreviations

<b>AMC</b>	Academic Medical Centers	<b>SSIC</b>	Swiss Science and Innovation Council
<b>ANR</b>	Agence Nationale de la Recherche	<b>SSTC</b>	Swiss Science and Technology Council
<b>BITg</b>	Biotechnologie Institut Thurgau	<b>SVRI</b>	Swiss Vaccine Research Institute
<b>CHF</b>	Swiss Franc	<b>SwissTPH</b>	Swiss Tropical and Public Health Institute
<b>CHU</b>	Centre hospitalier universitaire – university hospital centre	<b>USA</b>	United States of America
<b>CRO</b>	Contract Research Organisation	<b>USD</b>	United States Dollar
<b>CIP</b>	Cooperation and Innovation Project	<b>USI</b>	Università della Svizzera italiana
<b>CTI</b>	Commission for Technology and Innovation	<b>USMLE</b>	United States Medical Licensing Examination
<b>CTU</b>	Clinical Trial Unit	<b>WHO</b>	World Health Organisation
<b>DNA</b>	Deoxyribonucleic Acid		
<b>ECRIN</b>	European Clinical Research Infrastructures Network		
<b>EPFL</b>	Swiss Federal Institute of Technology, Lausanne		
<b>ESF</b>	European Science Foundation		
<b>ERI</b>	Education, Research, Innovation		
<b>ETH</b>	Swiss Federal Institute of Technology		
<b>ETHZ</b>	Swiss Federal Institute of Technology, Zurich		
<b>FMI</b>	Friedrich Miescher Institute for Biomedical Research		
<b>FOPH</b>	Federal Office of Public Health		
<b>FSO</b>	Federal Statistical Office		
<b>IOR</b>	Institute of Oncology Research		
<b>IRB</b>	Institute for Research in Biomedicine		
<b>IRO</b>	Institut de recherche en ophtalmologie		
<b>LCME</b>	Liaison Committee on Medical Education		
<b>MD-PhD</b>	Medical Doctor-Doctor of Philosophy		
<b>NIH</b>	National Institutes of Health		
<b>NCCR</b>	National Centre of Competence in Research		
<b>R&amp;D</b>	Research and Development		
<b>RIPA</b>	Research and Innovation Promotion Act		
<b>RMS</b>	Robert Mathys Foundation		
<b>SAKK</b>	Swiss Group for Clinical Cancer Research		
<b>SAMS</b>	Swiss Academy of Medical Sciences		
<b>SBA</b>	Swiss Biotech Association		
<b>SCAHT</b>	Swiss Centre for Applied Human Toxicology		
<b>SCCL</b>	Swiss Cancer Center Lausanne		
<b>SCTO</b>	Swiss Clinical Trial Organisation		
<b>SERI</b>	State Secretariat for Education, Research and Innovation		
<b>SIAF</b>	Swiss Institute of Allergy and Asthma Research		
<b>SIB</b>	Swiss Institute of Bioinformatics		
<b>SME</b>	Small and Medium-sized Enterprises		
<b>SNSF</b>	Swiss National Science Foundation		
<b>SPF</b>	Swiss Paraplegic Research		

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