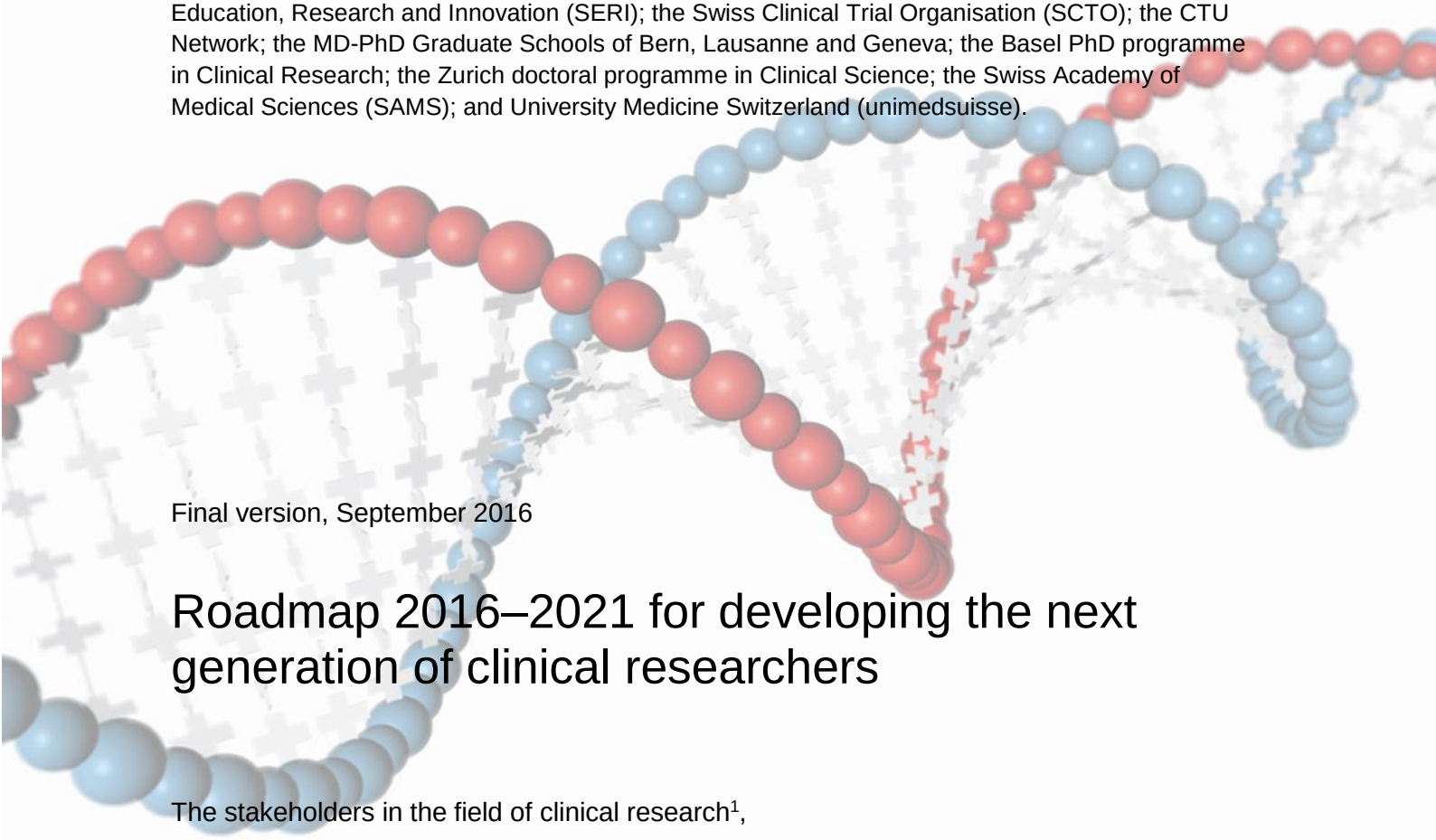
Prepared under the aegis of the Federal Office of Public Health (FOPH); the State Secretariat for Education, Research and Innovation (SERI); the Swiss Clinical Trial Organisation (SCTO); the CTU Network; the MD-PhD Graduate Schools of Bern, Lausanne and Geneva; the Basel PhD programme in Clinical Research; the Zurich doctoral programme in Clinical Science; the Swiss Academy of Medical Sciences (SAMS); and University Medicine Switzerland (unimedsuisse).



Final version, September 2016

Roadmap 2016–2021 for developing the next generation of clinical researchers

The stakeholders in the field of clinical research[1],

in support of the Federal Council's efforts to strengthen biomedical research and technology in Switzerland;

conscious of the fact that clinical research[2] is the critical link between bench and bedside, and a prerequisite for advancing our understanding, prevention and treatment of disease;

appreciating the efforts to strengthen clinical research in Switzerland that have been made in recent years;

recognising the particular importance of scientifically well-educated and well-trained research-oriented physicians for biomedical research, technology and innovation;

taking into account the recommendations of the 2014 SAMS/FOPH report on promoting the development of young physicians in the field of clinical research;

with the objective of providing educational and training structures and opportunities that make it possible to attract more and better trained junior staff into the pipeline for clinical research;

hereby declare their joint intention to design and implement systematic support for clinical research-oriented physicians at each stage of their career path.

[1] For a detailed list of contributors to this Roadmap, see the Annex on page 10.
[2] In the context of this Roadmap, clinical research is understood in its broadest sense, encompassing not only research as defined in the Human Research Act (HRA, Art. 2: research concerning human diseases and the structure and function of the human body, which involves persons, deceased persons, embryos and foetuses, biological material and health-related personal data), but also research with anonymised biological material and anonymously collected or anonymised health-related data, to which the HRA does not apply.

I. Executive summary

In 2013, the platform “Future of Medical Education” established a working group led by the Swiss Academy of Medical Sciences (SAMS) and the Federal Office of Public Health (FOPH) to elaborate recommendations as to how clinical research can be improved and further strengthened in Switzerland. The reason for this action, mandated by the Federal Council under the Masterplan to strengthen Biomedical Research and Technology in Switzerland, was the long-standing criticism that clinical research in Switzerland does not have the same high reputation as basic research. As a result, clinical research has not previously been regarded as an attractive career option, and not enough talented young physicians have focused on clinical research activities. However, given that Switzerland must remain and continuously develop as an attractive place for clinical research, investments designed to strengthen clinical research and increase interaction between basic and clinical research will generate added value in these fields.

The SAMS/FOPH report (including recommendations) was published in 2014. A task force was then appointed to develop specific measures, define responsibilities, and lay out a realistic time line for successful and sustainable implementation of the recommendations made in the report, within the framework of a national Roadmap, broadly supported by clinical research players and stakeholders in Switzerland.

To ensure systematic support for research-oriented clinicians at each stage of their medical career path, the following Work Packages (WP) are planned:

Recommendation in SAMS/FOPH report “Nachwuchs für die Klinische Forschung / Relève pour la recherche clinique” (09.2014)	**Work Package (WP) in the present Roadmap** “Roadmap 2016–2021 for developing the next generation of clinical researchers” (09.2016)
1. Early identification and encouragement of research-oriented medical students Objective: Research-oriented medical students are identified and given the opportunity to deal with clinical research topics	**Level Education** WP 1 – Collaboration with local MD-PhD Graduate Schools WP 3 – Swiss Clinical Research Education Centre
2. Optimal professional qualifications during specialist training Objective: Research-oriented doctors have the opportunity to acquire professional qualifications and expertise in clinical research (in parallel with medical specialisation)	**Level Specialisation** WP 2 – Minimum standards for clinical research skills WP 3 – Swiss Clinical Research Education Centre WP 4 – Funding programme for physicians in clinical research (starter grants)
3. Improvement of working conditions and career opportunities Objective: Research-friendly working/employment conditions in hospitals, as well as career opportunities for clinical researchers	**Level Establishment** WP 5 – Research-friendly conditions of employment and career opportunities

In the interests of efficiency and to avoid duplication, the planned activities build on existing infrastructures and expertise in the field. The proposed time frame for elaboration and preparation of the planned measures is 2016–2018. A comprehensive framework for clinical research education and support will be available from the autumn semester 2018 onwards. A three-year pilot period will be closely monitored and followed by an evaluation.

The overall goal of the joint endeavour is to develop the next generation of clinical researchers in Switzerland.

II. Background

In 2013, the platform "Future of Medical Education"[3] established a working group led by the Swiss Academy of Medical Sciences (SAMS) and the Federal Office of Public Health (FOPH) to elaborate recommendations as to how clinical research can be improved and further strengthened in Switzerland. The reason for this mandate was the long-standing criticism that clinical research in Switzerland does not have the same high reputation as basic research. The working group consulted various stakeholders and conducted a broad survey to assess the general state of clinical research – in particular, the overall quality of clinical research, the framework conditions, the requirements concerning clinical research in medical education and postgraduate training, and the provision of support for young physicians in the field of clinical research. The SAMS/FOPH report[4], published in 2014, concludes that especially support for young physicians needs further improvement so as to ensure that more and better trained junior staff get into the pipeline for clinical research and academic medicine, that research-oriented physicians have the opportunity to acquire professional qualifications and expertise in clinical research in parallel with their medical specialisation, and that clinical research becomes more compatible with daily hospital routine. In addition, the report calls for systematic support for research-oriented clinicians at each stage of their career path and concludes with three concrete recommendations (including possible measures) to improve the situation (see Annex).

In August 2015, a task force[5] – led by the FOPH and comprising representatives of the medical faculties, University Hospitals, SAMS, SCTO and the pharma industry – was appointed to develop specific measures, define responsibilities, and lay out a realistic time line for successful and sustainable implementation of the recommendations made in the 2014 report, within the framework of a national Roadmap, broadly supported by the relevant players and stakeholders. The present roadmap was therefore reviewed by a sounding board[5] including stakeholders who were not directly involved in its elaboration but are of great importance for developing the next generation of clinical researchers.

Given that scientifically well-educated and well-trained research-oriented physicians play a key role in bridging the interface between basic and clinical research and thus represent the human capital for biomedical research, technology and innovation, the elaboration of the SAMS/FOPH report and the present roadmap was mandated by the Federal Council under the Masterplan to strengthen Biomedical Research and Technology in Switzerland[6]. By way of public consultation, a draft of the roadmap was presented at the 7th SCTO Symposium, held in Lausanne on 16 June 2016. The feedback received from the scientific community was summarised in a consultation report and carefully taken into consideration in the preparation of the final document. The consolidated version of the Roadmap was officially approved by the task force in September 2016.

Clinical research promotion throughout the medical career track

The recommendations of the 2014 SAMS/FOPH report address all phases of a career in academic medicine – medical studies, specialist training, and the period between receiving a specialist title and being appointed to a professorship (see Figure 1). The current structure of medical studies (three years' basic training for the Bachelor of Medicine, followed by three years' studies for the Master of Medicine), allows students to choose more scientifically oriented training during the education phase. Some universities offer training modules focusing on clinical research during the Master's programme. The Master's thesis provides an opportunity to acquire (initial) practical research skills. To facilitate career mentoring and to prevent delays at a later stage, the report recommends that medical students interested in research should be identified, encouraged and introduced to the field of clinical research as early as possible.

[3] Plattform "Zukunft ärztliche Bildung" (http://www.bag.admin.ch/themen/berufe/11724/)
[4] Nachwuchs für die Klinische Forschung in der Schweiz (2014). The joint SAMS/FOPH report is available in German and French at: http://www.bag.admin.ch/themen/berufe/11724/14206/?lang=de and http://www.bag.admin.ch/themen/berufe/11724/14206/index.html?lang=fr
[5] For a detailed list of contributors to this Roadmap, see the Annex on page 10.
[6] Massnahmen des Bundes zur Stärkung der Biomedizinischen Forschung und Technologie. This document is available in German and French at: www.bag.admin.ch/en/masterplan

The majority of medical students who successfully complete their studies enter postgraduate training in order to obtain a medical specialist title[7]. During the specialisation phase, research-oriented physicians have to meet various expectations and reconcile specialist training, daily hospital routine, the acquisition of research skills and the conduct of clinical research activities. Depending on the scope of research activities and the level/depth of training (e.g. CAS, DAS, MAS, PhD), completion of the specialisation phase may be considerably prolonged. The report recommends that research-oriented physicians in specialist training should have the opportunity to acquire appropriate professional qualifications and expertise in clinical research.

Figure 1: Possibilities for promoting the development of research-oriented physicians at the various stages of their career

In order to attract talented young physicians and retain them in the field of clinical research, the report states that research-friendly structures and conditions of employment at (university) hospitals are of great importance. Especially during the phase of establishment as a (senior) researcher, greater latitude for clinical research – e.g. through release from daily hospital routine – is crucial. In addition, there is a need for more, and more visible, career opportunities for clinical researchers – also outside academia.

Since the elaboration of the SAMS/FOPH report in 2013, many of the issues raised have already been addressed. At the Medical Faculties, various strategies are in place for the identification and recruitment of medical students interested in research, especially regarding the promotion of MD-PhD programmes, most of which are now also open for clinical research projects. In 2014, the Department of Clinical Research in Basel established the first PhD programme in Clinical Research open for physicians, and the Medical Faculty in Zurich recently launched a PhD programme in Clinical Science. Opportunities to acquire professional qualifications and expertise in the field of clinical research have been considerably enhanced by the further establishment of the Clinical Trial Units (CTUs) and the SCTO, the continuous expansion of departments of clinical research, and the increased number and range of clinical research courses and training programmes available. Most professional medical associations recognise the added value of research activities during specialisation and credit 6–12 months of (patient-oriented) research time for specialist medical training (especially when research is conducted within the framework of an MD-PhD programme). It is worth noting that in Switzerland, in contrast to many European countries, a specialist title in pharmaceutical medicine exists: here, the training objectives place considerable emphasis on the planning, conduct and interpretation of clinical studies to advance the clinical development of new therapeutic options, as well as ongoing benefit/risk evaluation. In autumn 2015, the SNSF launched the initiative “Protected Research Time for Clinicians” as an associated funding instrument[8]. The initiative is intended to help clinicians to dedicate at least

[7] Currently, there are 43 federally approved medical specialist titles, plus the federal title “medical practitioner”.
[8] Eligible are active clinicians at Swiss hospitals who have received SNSF funding for a research project. http://www.snf.ch/en/funding/supplementary-measures/protected-research-time-clinicians/Pages/default.aspx#

30% of their working hours to their SNSF-funded research project. With regard to research-friendly conditions of employment and career opportunities in clinical research, efforts are being made at many locations to increase the number of positions and assistant professorships with a contractually stipulated percentage of research time.

All of the above-mentioned developments significantly contribute to making the clinical research career path more attractive and strengthening Switzerland as a clinical research location. However, the wide variety of training possibilities, the different conditions and specific requirements of individual sites, and the challenges that arise when clinical research is combined with medical specialisation mean that it remains difficult for physicians to envisage, plan and efficiently pursue a career in clinical research. Furthermore, fellowships, project grants and protected time are mainly provided to advanced rather than junior researchers, leaving gaps in the research-oriented medical career path.

III. Work Packages and responsibilities

The following five key Work Packages (WP) were elaborated in accordance with the recommendations of the SAMS/FOPH report and take into account developments since the preparation of the report:

- WP 1 – Collaboration with local MD-PhD Graduate Schools
- WP 2 – Minimum standards for clinical research skills
- WP 3 – Swiss Clinical Research Education Centre (SCREC)
- WP 4 – Funding programme for physicians in clinical research
- WP 5 – Research-friendly conditions of employment and career opportunities

The WPs are described in more detail below.

Work Package 1 – Collaboration with local MD-PhD Graduate Schools

The Swiss MD-PhD programmes have a long tradition – among the longest in Europe. Since 1992, physicians in Switzerland have been able to do a PhD in biomedical sciences (amongst others) together with a training programme supervised by so-called Interfaculty Steering Committees, with representatives from the Science, Medicine, and Vetsuisse Faculties. Three of the five MD-PhD programmes have recently been opened to candidates with clinical research projects. The other two locations have developed separate PhD programmes in Clinical Science, which are open for physicians. Since individual training modules or entire courses with a clinical research focus, offered by the CTU network, could also be integrated into the MD-PhD programmes, close collaboration between the SCREC (WP 3), the CTUs and the MD-PhD Graduate Schools would be appropriate.

Milestones:

1 (2/2017)	The need for further action is defined, solutions are elaborated for fruitful collaboration between MD-PhD-programmes and the SCREC.
2 (09/2017)	Solutions are implemented. Each of the five locations (BE, BS, GE, LS, ZH) offers an MD-PhD programme that supports students with clinical research projects.

Responsibility: The local MD-PhD Graduate Schools offer the possibility to obtain an MD-PhD degree in clinical research at all five locations. The SCREC is responsible for the maintenance of collaboration.

Work Package 2 – Minimum standards for clinical research skills

In order to facilitate the acquisition of uniform professional qualifications, minimum standards for clinical research skills will be defined. These standards are intended to be used as a reference for guidance of research-oriented physicians and will encompass the necessary skills (including a short description of content and credit points assigned) which are to be acquired through theoretical and practical training. To assist candidates in choosing appropriate training programmes for their individual purposes, a comprehensive, up-to-date overview of relevant training programmes (e.g. CAS, DAS, MAS, PhD, or modules thereof) will be provided by the SCREC (WP 3). This overview will be

complemented by information on how each training programme contributes to the defined minimum standards.

Milestones:

1 (6/2017)	Minimum standards are defined for skills, including content description and credit points for theoretical and practical training.
2 (9/2017)	An overview of relevant courses and training programmes is available online.

Responsibility: The education experts of the CTUs, who are responsible for most of the courses currently offered in clinical research, will form a working group with support from the SCTO Executive Office to elaborate minimum standards for clinical research skills.

Work Package 3 – Swiss Clinical Research Education Centre

While the existing courses and training programmes are already comprehensive, efforts must be made to optimally embed them into an overall framework for clinical research education designed to:

- grant substantial and sustained support for trainees during the specialisation phase (professional support, administrative support, financial support and career mentoring);
- provide a common structure and a pre-organised schedule/procedure for training and education;
- achieve the greatest possible compatibility with all types of medical specialist training;
- prevent undue prolongation of the specialisation phase;
- facilitate mobility of research fellows throughout Switzerland.

To realise these objectives, a virtual school – the Swiss Clinical Research Education Centre (SCREC) – will be established, building on existing infrastructures and expertise. The SCREC will be part of the SCTO and its CTU network, since the network is already a major provider of clinical research training and mentoring services.

The SCREC will provide the necessary framework for efficient acquisition of professional qualifications and expertise in clinical research. It will coordinate local courses or services at the national level, advise students and young physicians on clinical research training and link them to the CTU network, as well as facilitating and supporting the development of training programmes. The SCREC will promote clinical research education and career options under one branding through information events, contributing to the earliest possible recruitment of medical students interested in research. Furthermore, the SCREC will provide additional services and promotion activities for young research-oriented physicians, such as a career mentoring programme and supplementary courses (e.g. presentation skills, writing grant applications, scientific writing, etc.), as well as assistance with mobility issues. Provided that financial resources can be made available, a starter-grant fellowship programme (WP 4) will also be administered through the SCREC. To motivate future clinical researchers for research projects and a career in clinical research, the SCREC will be in continuous contact with the Medical Faculties to strengthen and implement new focal points in career track development.

Milestones:

1 (2/2017)	Governance, activity portfolio and required funding are defined.
2 (02/2018)	Activities are implemented as planned, financing and human resources are secured. Official start of services.

Responsibility: The SCTO will be responsible for setting up and running the SCREC.

Work Package 4 – Funding programme for physicians in clinical research (starter grants)

Supporting clinical research activities and promoting the development of talented young physicians in this field is time-consuming and costly, and such efforts are strongly dependent on the availability and distribution of resources, as well as on additional (e.g. cantonal, third-party) financial support for

clinical research at university hospitals. The SNSF mostly provides grants and protected time for advanced researchers, who already have a certain track record. To remedy this deficiency in the research-oriented medical career path, a (pilot) funding programme sponsored by private foundations and/or industry will award starter grants to promising candidates who enter a training programme through the SCREC, via a competitive selection procedure. Depending on the experience gained during the first years of this funding programme (regarding demand, feasibility, output, but also successful integration of grant holders into clinical research structures), the results of this pilot could provide the basis for a subsequent application to public funding bodies.

Milestones:

1 (2/2017)	A funding programme concept is elaborated, the financial requirements are defined, and fundraising is started.
2 (02/2018)	If fundraising efforts are successful: Framework conditions are defined, regulations are approved and the first call is launched for candidates to start the programme in autumn 2018.

Responsibility: The SAMS will be responsible for the form (content and financial resources), management and further development of the funding programme.

Work Package 5 – Research-friendly conditions of employment and career opportunities

Young clinical researchers are supposed to assume leadership roles in the various departments of a university hospital. However, recruiting physicians for such positions is a problem for most university hospitals. Developing attractive employment conditions and career opportunities for young clinical researchers should therefore be considered by university hospitals as a win-win initiative. This implies a bottom-up process that starts in clinical departments with the identification of potential candidates, continues with the establishment of a dual path allowing clinical specialisation in parallel with academic activities (chief of service, along with the medical and academic authorities), and ends with a formal, personalised career plan and specific mentoring. This also implies that protected time can be provided by the university hospitals and financial support for the academic salary can be guaranteed by sources that may include hospitals' training budgets, the universities, the SNSF and private foundations.

Through WP 5, the Medical Faculties and University Hospitals will jointly elaborate a concept for the establishment of attractive employment conditions and career opportunities for young clinical researchers, taking into account the various existing recommendations[9–12]. WP5 is considered to be of the highest priority: the overall impact of the Roadmap will depend on the successful implementation of WP5.

Milestones:

1 (06/2018)	A concept is jointly elaborated for research-friendly conditions of employment and career opportunities at university hospitals.

Responsibility: The association "University Medicine Switzerland" (unimedsuisse) will be responsible for the elaboration of a concept for improving the conditions of employment and career opportunities at university hospitals.

[9] Medicine as a science. Position paper of the Swiss Academy of Medical Sciences (2009).
[10] Empfehlungen für gendergerechte akademische Karrierewege. Akademien der Wissenschaften Schweiz (2016)
[11] SAMS/FOPH report (2014). See Footnote 4.
[12] Culture of research and support for young scientists in medicine. SAMS Position paper (2016).

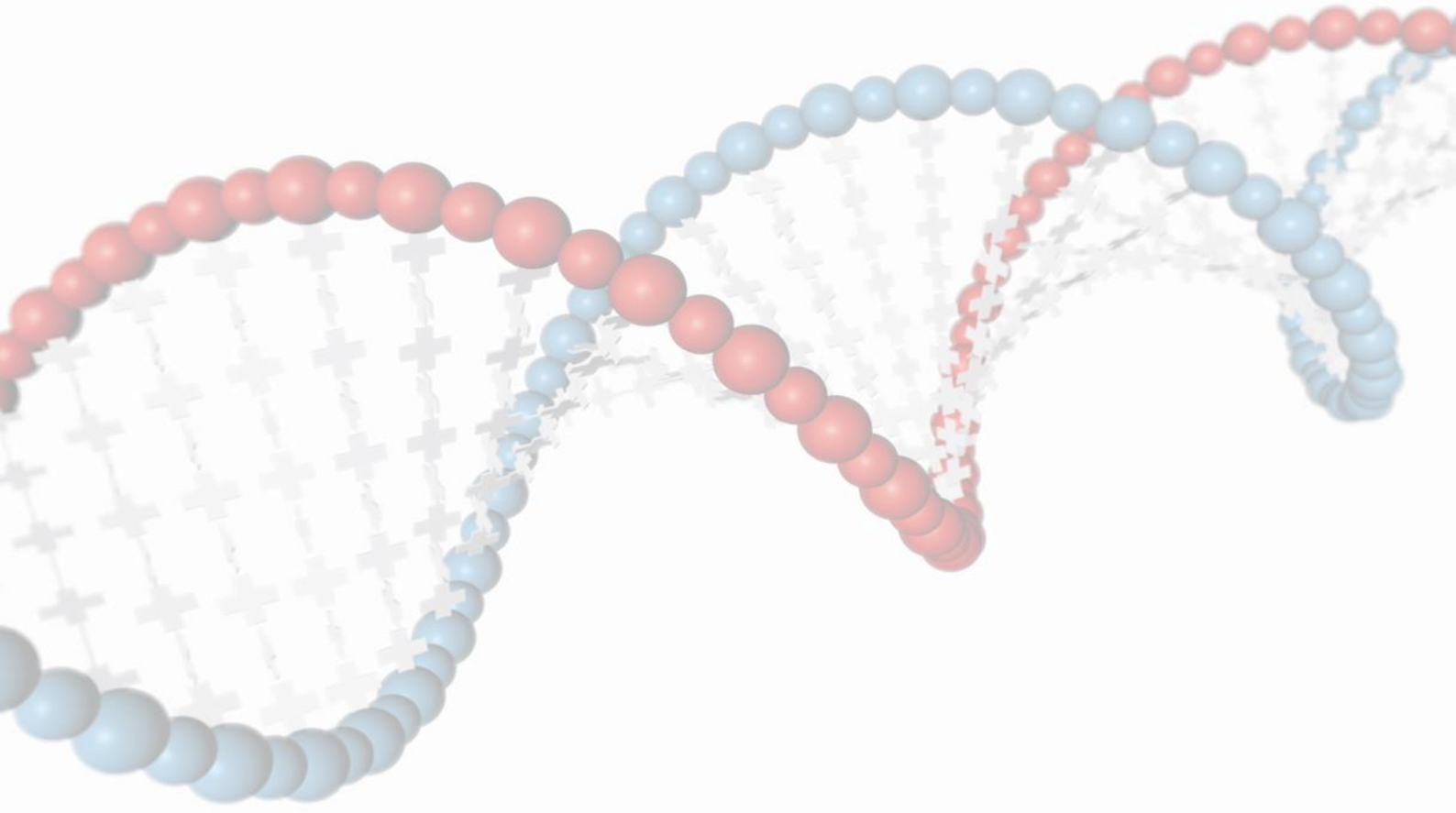
IV. General conditions and future outlook

Responsibilities: The SCTO together with the FOPH will be responsible for overall coordination of the Roadmap. If considered necessary, the FOPH may convene additional meetings of the task force (or other groups).

Time frame: The proposed time frame for elaboration and preparation of the planned measures is 2016–2018. The target date for implementation of the national framework for clinical research education is the beginning of the autumn semester 2018.

Financial aspects: Currently, no federal funding is available for the implementation of WP activities. Financing depends on the organisations involved in the realisation of the Roadmap. The objectives were established in close collaboration with all the organisations directly concerned. They are thus in line with the strategies of these organisations, which are in general prepared to allocate the required budget to the planned activities. However, depending on the individual organisation's financial situation, adjustments may be required and/or further funding sources may need to be identified.

Future outlook: A three-year pilot period (09/2018–09/2021) will be closely monitored and followed by an evaluation. The FOPH will coordinate this evaluation and provide the required financial resources, subject to budgetary decisions of the Federal Council and Parliament. The evaluation report will provide the basis for adjustment of the framework and its portfolio, for preparation of a subsequent funding solution for the starter-grant programme, and for consideration of new and/or follow-up activities.
Depending on the evaluation report, the further development or introduction of new measures can be undertaken in close collaboration with key partners (e.g. universities, SIWF/ISFM, specialist associations, etc.), also with a view to sharing of experience and coordination/harmonisation of activities.



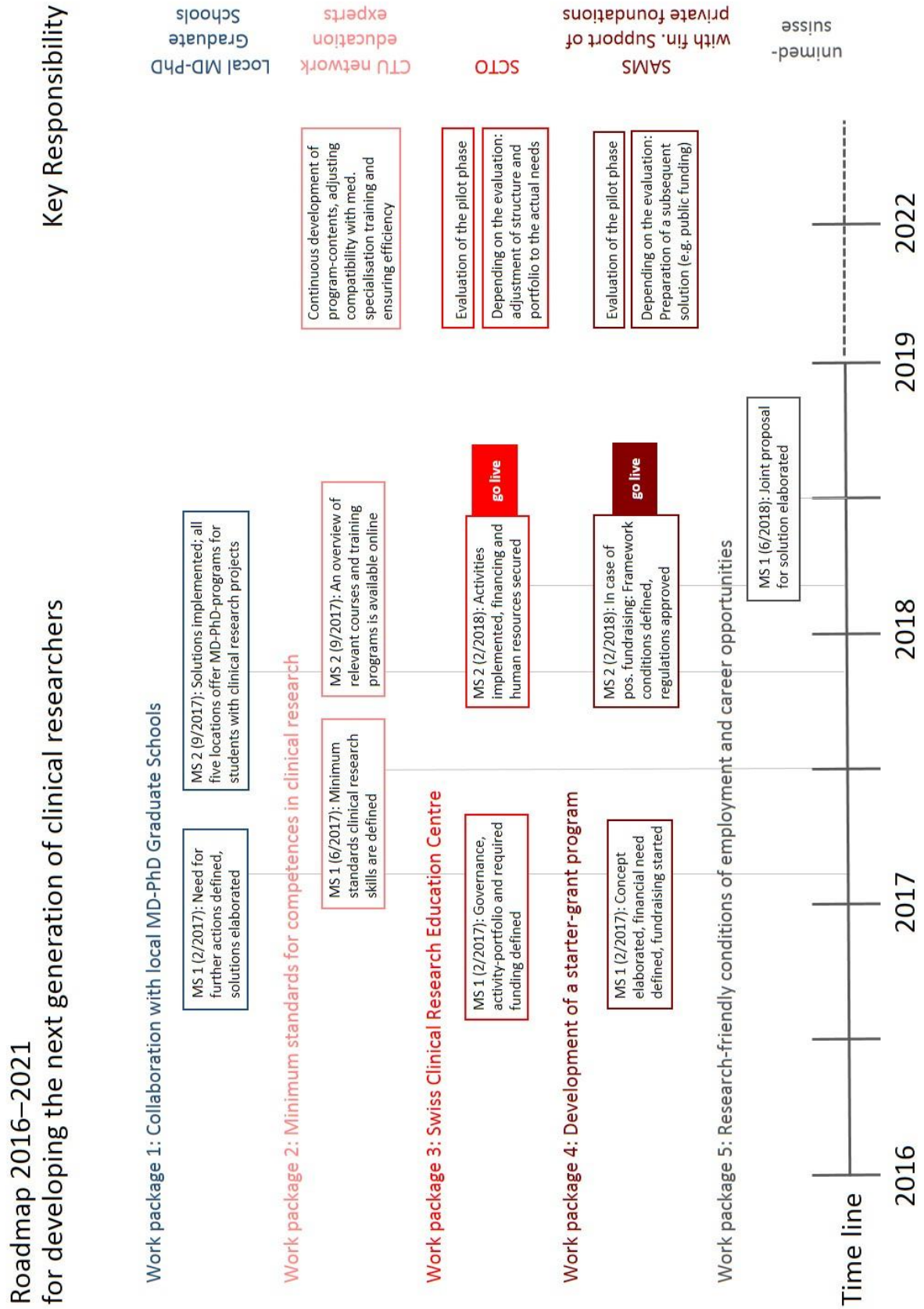


Figure 2: Roadmap illustration

V. Annex

Recommendations of the 2014 SAMS/FOPH-report

Education
Medical students interested in research should be identified, encouraged and introduced to the field of clinical research as early as possible.

Measures:
- Launching of events/measures to identify and motivate research-oriented students.
- Offering of courses to provide qualifications/track record in clinical research during the Master's programme.
- Courses in clinical research to be offered within the framework of MD-PhD programmes.

Training/specialisation
Research-oriented physicians in specialist medical training should have the opportunity to acquire professional qualifications and expertise in clinical research.

Measures:
- The specifications concerning physicians' research skills (in the SCLO, Healthcare Professions Act/MedBG and Postgraduate Training Regulations/WBO) are revised accordingly.
- 1 year of clinical research is credited in all specialist training programmes.
- Integration of existing training opportunities in clinical research.

Establishment
Research-friendly working/employment conditions are required in hospitals, as well as career opportunities for clinical researchers.

Measures:
- Provision of positions for assistant and senior physicians with a contractually stipulated percentage of research time.
- Introduction of "protected time" with SNSF funding.
- Creation of (additional) Assistant Professorships with at least 50% research time.

Contributors to the Roadmap

Members of the task force:
- Henri Bounameaux, University of GE
- Katrin Crameri, FOPH
- Matthias Gugger, University Hospital BE
- Annette Magnin, SCTO
- Peter Meier-Abt, SAMS
- Vincent Mooser, CHUV, Lausanne
- Christiane Pauli-Magnus, Univ. Hospital BS
- Barbara Peters, University Hospital BS
- Arnaud Perrier, HUG, GE
- Gabriel Schnetzler, Roche (*ad personam*)
- Gregor Zünd, University Hospital ZH
- Gabriela Senti, University Hospital ZH

Institutions and organisations represented on the sounding board:
SERI, FOPH, SNSF, Swissethics, SCTO, Oncosuisse/SAKK, SAMS, GDK/CDS, unimedsuisse, swissuniversities, local MD-PhD Graduate Schools, FMH, SIWF/ISFM, SGPM/ASMP, ECPM, SwAPP, SPO Patientenschutz, Dachverband Schweizerischer Patientenstellen, santésuisse, Curafutura, Interpharma, vips, scienceindustries, Intergenerika, FASMED, IG Schweizer Pharma KMU, Swiss Biotech Association