Roadmap 2016-2021 for Building up the Future Generation of Clinical Researchers

The stakeholders in the field of clinical research¹,

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

*conscious of* the fact that clinical research² is the critical link between bench and bedside and the prerequisite for advancing our understanding, prevention and treatment of disease;

*appreciating* the efforts to strengthen clinical research in Switzerland that have been made over the last years;

*recognizing* the particular importance of scientifically well-educated and well-trained research-oriented medical doctors for biomedical research, technology and innovation;

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

*with the objective* of providing structures and perspectives of education and training that allow to attract more and better specialized junior staff into the pipeline for clinical research;

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

¹ A detailed list of the contributors to this Roadmap is displayed in the attachment of this document on page 9.
² In the context of this Roadmap, clinical research is understood in its broadest sense, and does not only encompass research within the scope of 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 as well as health-related personal data), but also includes 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” engaged a working group under the lead of the Swiss Academy of Medical Sciences (SAMS) and the Federal Office of Public Health (FOPH) to elaborate recommendations on how clinical research in Switzerland can be improved and further strengthened. The reason for this mandate of the Federal Council, commissioned within the framework of the Masterplan to strengthen Biomedical Research and Technology in Switzerland, was the long-standing criticism that clinical research in Switzerland has not the same high reputation as basic research. As a consequence, clinical research has not been regarded as a very attractive career option in the past and therefore not enough young talents put their focus on clinical research activities. However, Switzerland should stay and continuously develop as an attractive place for clinical research. Strengthening clinical research and more interaction between basic and clinical research will generate added value out of the investments in these fields.

The SAMS/FOPH-report with recommendations was published in 2014. As a consequence, a task-force was appointed to concretise the appropriate measures, define the responsibilities, and lay out a realistic time line for a successful and sustainable realization of the 2014-report recommendations within the framework of a national Roadmap, broadly supported by the players and stakeholders in the field of clinical research in Switzerland.

In furtherance of a systematic support of research-oriented clinicians in each stage of their medical career path, the following Work Packages (WP) are planned:

<table>
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<tr>
<th>Recommendation SAMS/FOPH-report</th>
<th>Work Package (WP) in the present Roadmap</th>
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1. Early identification and promotion 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 qualification during advanced training
   - Objective: Research-oriented doctors have the opportunity to acquire professional qualification and competences within the field of clinical research (in parallel to their medical specialisation)
   - Level specialisation
   - WP 2 – Minimum standards for competences in clinical research
   - WP 3 – Swiss Clinical Research Education Centre
   - WP 4 – Funding program for physicians in clinical research (starter-grants)

3. Improvement of working conditions and career opportunities
   - Objective: Research-friendly working and 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 interest of efficiency and to avoid duplication, the planned activities are building up on existing infrastructures and expertises in the field. The proposed time frame for elaboration and preparation of the planned measures is 2016-2018. A comprehensive framework structure for clinical research education and support will be available from the fall semester 2018 on. A pilot period of three years will be closely accompanied and followed by an evaluation.

The overall goal of the joint endeavour remains to build-up the future generation of clinical researchers in Switzerland.
II. Background

In 2013, the platform “Future of Medical Education”\(^3\) engaged a working group under the lead of the Swiss Academy of Medical Sciences (SAMS) and the Federal Office of Public Health (FOPH) to elaborate recommendations, how clinical research in Switzerland can be improved and further strengthened. The reason for this mandate was the long-standing criticism that clinical research in Switzerland has not the same high reputation as basic research. The group consulted various stakeholders and conducted a broad survey to assess the general state of clinical research, namely the overall quality of clinical research, the framework conditions, the requirements in education and postgraduate medical training concerning clinical research as well as the promotion of young physicians in the field of clinical research. The SAMS/FOPH-report\(^4\) was published in 2014 and concludes that especially the promotion of young physicians needs further improvement in a sense that more and better specialized junior staff gets into the pipeline for clinical research and academic medicine, research-oriented doctors have the opportunity to acquire professional qualification and competences within the field of clinical research in parallel to their medical specialization, and the compatibility of clinical research and daily routine in the clinic improves. Moreover, the report calls for a systematic support of research-oriented clinicians in each stage of their career path and concludes with three concrete recommendations and potential measures to improve the situation (see attachment).

In August 2015, a taskforce\(^5\) with representatives of the medical faculties, University Hospitals, SAMS, SCTO and Pharma Industry under the lead of the FOPH was appointed to concretise the required measures, define the responsibilities, and lay out a realistic time line for a successful and sustainable realization of the 2014-report recommendations within the framework of a national Roadmap, broadly supported by the players and stakeholders in the field. The present roadmap was therefore reviewed by a sounding board\(^6\), encompassing stakeholders, who were not directly involved in its elaboration, but are of great importance for building up the future generation of clinical researchers.

With regards to the fact that scientifically well-educated and well-trained research-oriented medical doctors play a key role in bridging the interface of basic and patient-oriented research and therefore represent the human capital for biomedical research, technology and innovation, the elaboration of the SAMS/FOPH-report as well as the present roadmap were mandates of the Federal Council, commissioned within the framework of the Masterplan to strengthen Biomedical Research and Technology in Switzerland\(^6\). In the sense of a public consultation process, a concerted draft of the roadmap was presented during the 7th SCTO-Symposium held on June 16, 2016 in Lausanne. The feedback of the scientific community was carefully taken in consideration for the refinement of the document. The taskforce officially approved the consolidated version of this roadmap in July 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: the period of the medical studies, the phase of specialist medical training, and the time span between having received a medical specialist title and the appointment to a professorship (see Figure 1). The current structure of the medical studies (three years’ basic training for the Bachelor of Medicine, followed by three years’ master studies for the Master in Medicine), allows students to choose a more scientifically oriented training, already during the education phase. Some Universities even offer training modules with a particular focus on clinical research during the Master program. The Master

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3 Plattform „Zukunft ärztliche Bildung“ [http://www.bag.admin.ch/themen/berufe/11724/]
5 A detailed list of the contributors to this Roadmap is displayed in the attachment of this document on page 9.
thesis provides the opportunity to acquire (first) practical research competences. In the sense of a career-mentoring and to prevent delays later in the career, the report recommends that research-oriented medical students should be identified, encouraged and introduced to the field of clinical research as early as possible.

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

In order to attract young talents and retain them in the field of clinical research, the report states that research-friendly structures and conditions of employment at the (University) Hospitals are of great importance. Especially during the phase of establishment as a (senior) researcher, a greater latitude for clinical research, e.g. through the release from daily routine in the clinic, is crucial. Moreover, more and better visible career opportunities for clinical researchers – also outside the academic world – are necessary.

Since the elaboration of the SAMS/FOPH-report in 2013, many of the issues addressed have already been approached. At the Medical Faculties, various identification and recruitment strategies to reach research-oriented medical students are in place, especially regarding the promotion of the MD-PhD programs, most of which are nowadays also open for clinical research projects. In 2014, the Department of Clinical Research in Basel established the first PhD program in clinical research open for medical doctors, and the medical faculty in Zurich is about to launch a program for a PhD in Clinical Science. Especially the further establishment of the CTUs and the SCTO, the continuous extension of the departments of clinical research, as well as the increased number and range of courses and training programs offered in the area of clinical research considerably contributed to an improvement regarding the opportunity to acquire professional qualification and competences within the field of clinical research. Most professional medical associations recognize the added-value of research-activities during the specialisation phase and credit between 6 to 12 months of (patient-oriented) research time for the specialist medical training (especially when research is done within the framework of an MD-PhD

\(^7\) Currently, there are 43 federally approved medical specialist titles plus the federal title “medical practitioner”.
program). It is worthwhile to note that in Switzerland, in contrast to many European countries, a medical specialist title in pharmaceutical medicine exists: the training objective puts a lot of emphasis on planning, conduct and interpretation of clinical studies in order to advance clinical development of new therapeutic options, as well as on their ongoing benefit/risk evaluation. In fall 2015, the SNSF launched the initiative “Protected Research Time for Clinicians” as associated funding instrument. The initiative is intended to help clinicians to dedicate at least 30% of their working hours to their SNF-funded research project. Concerning the research-friendly conditions of employment and career opportunities in the field of clinical research, efforts are being made at many locations to increase the number of positions and assistant professorships with contractually stipulated percentage of research-time.

All of the above described developments significantly contribute to make the clinical research career path more attractive and strengthen Switzerland as a clinical research location. However, the great variety of training possibilities, the different conditions and specific requirements of the individual sites as well as the challenges that arise when combining clinical research with medical specialisation still make it difficult for medical doctors to envisage, plan and efficiently pursue a career in the field of clinical research. Furthermore, fellowships, project-grants and protected time are mainly provided to advanced rather than to junior researchers, leaving a gap in the promotion path along the research-oriented medical career.

### III. Work Packages of the roadmap and responsibilities

The following five key Work Packages (WP) were identified to comply with the recommendations of the SAMS/FOPH report and taking into account the developments since the publication of their report:

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

The WPs are subsequently described in more detail.

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

The Swiss MD-PhD programs have a longstanding tradition, one of the longest in Europe. Since 1992, medical doctors in Switzerland have the possibility to do a PhD in biomedical sciences flanked by a training program supervised by the “Interfaculty steering committees”, a collaboration of the Faculties of Science, the Faculties of Medicine, and the Vetsuisse Faculties. Three of the five MD-PhD programs have recently been opened to candidates with clinical research projects. The other two locations developed separate PhD programs in clinical science that are open for medical doctors. Since single training-units up to entire courses with clinical research focus, offered by the CTU network, could also be integrated into the MD-PhD programs, a close collaboration of the SCREC (WP 3), the CTUs and the MD-PhD Graduate Schools is expedient.

#### Milestones:

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<tr>
<th>Number</th>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>12/2016</td>
<td>The need for further actions is defined, solutions for a fruitful collaboration between the MD-PhD-programs and the SCREC are elaborated</td>
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<tr>
<td>2</td>
<td>09/2017</td>
<td>Solutions are implemented. Each of the five locations (BE, BS, GE, LS, ZH) offers an MD-PhD program that supports students with clinical research projects</td>
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#### Responsibility: The local MD-PhD Graduate Schools grant the possibility to obtain an MD-PhD degree in clinical research at all five locations. The SCREC is responsible for the maintenance of the collaboration.

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8 Eligible are active clinicians at Swiss hospitals who received SNF-funding for a research project. [http://www.snf.ch/en/funding/supplementary-measures/protected-research-time-clinicians/Pages/default.aspx#](http://www.snf.ch/en/funding/supplementary-measures/protected-research-time-clinicians/Pages/default.aspx#)
Work Package 2 – Minimum standards for competencies in clinical research

In order to facilitate the acquisition of consistent professional qualifications, minimum standards for competences in clinical research will be defined. These standards are intended to be used as reference and orientation for research-oriented medical doctors and will encompass the necessary competences including a short content description and assigned credit points that will have to be acquired through theoretical and practical training. To assist candidates in choosing appropriate training programs for their individual purposes, a comprehensive and up-to-date overview of all relevant training programs (e.g. CAS, DAS, MAS, PhD, or modules of these programs) will be provided by the SCREC (WP 3). This overview will be complemented by the information of how each training program contributes to the defined minimum standards.

Milestones:

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<tr>
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<tr>
<td>1 (12/2016)</td>
<td>Minimum standards for competences with content description and credit points of theoretical and practical training are defined</td>
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<tr>
<td>2 (12/2016)</td>
<td>An overview of relevant courses and training programs is available online</td>
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Responsibility: The education experts of the CTUs, who are responsible for most of the currently offered courses in the field of clinical research, will constitute a working group with support of the SCTO executive office to elaborate minimum standards for competences in clinical research.

Work Package 3 – Swiss Clinical Research Education Centre

The existing courses and training programs are already comprehensive, however, efforts have to be made to optimally embed them into a framework structure for clinical research education that aims at:

- granting substantial and sustained support for trainees during the specialisation phase (professional support, administrative support, financial support, and career-mentoring);
- providing a common structure and a pre-organized schedule/procedure for training and education;
- reaching the greatest possible compatibility with all medical specialisation trainings;
- preventing an extensive prolongation of the specialisation phase;
- facilitating mobility of fellows throughout Switzerland.

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

The SCREC will provide the necessary framework structure to efficiently acquire professional qualification and competences within the field of clinical research. It will coordinate locally offered courses or services nationally, advise students and young doctors concerning clinical research trainings and link them with the CTU network as well as facilitate and support the development of training programs. The SCREC will promote the education and career possibilities in clinical research under one branding through information events, contributing to an as early as possible recruitment of research interested medical students. Furthermore, the SCREC will provide additional service and promotion activities for young research-oriented doctors, such as a career-mentoring program, supplementary framework courses (like presentation skills, how to write a grant, scientific writing, etc.), as well as assistance concerning mobility issues. Provided that financial resources can be raised, a starter-grant fellowship program (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:

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<tbody>
<tr>
<td>1 (12/2016)</td>
<td>Governance, activity-portfolio and required funding is defined</td>
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<tr>
<td>2 (02/2018)</td>
<td>Activities are implemented as planned, financing and human resources are secured. Official start of the services</td>
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Responsibility: The SCTO will be responsible to set up and run the SCREC.
Work Package 4 – Funding program for physicians in clinical research (starter-grants)

The support of clinical research activities as well as the promotion of young talents in this field is time-consuming and cost-intensive and the efforts therefor strongly dependent on the availability and distribution of means as well as on the additional (e.g. cantonal, third party, etc.) financial support for clinical research at the university hospitals. The SNSF mostly provides grants as well as protected time to advanced researchers, who already have a certain track record. To remedy this deficiency in the promotion path along the research-oriented medical career, a (pilot) funding program sponsored by private foundations and/or industry will award starter grants to promising candidates, who enter a training program through the SCREC, through a competitive selection procedure. Depending on how this funding program shapes up, the experience gained during in the first years (regarding demand, feasibility, output, but also the successful integration of grant holders into the clinical research structures), the results of this pilot could build the basis for a later application to public funding bodies.

Milestones:

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<tbody>
<tr>
<td>1 (12/2016)</td>
<td>A concept of the funding program is elaborated, the financial need is defined, and the fundraising started</td>
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<tr>
<td>2 (02/2018)</td>
<td>In case of positive fundraising: Framework conditions are defined, regulations are approved and the first call for candidates to start the program in fall 2018 is launched</td>
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Responsibility: The SAMW will be responsible for form (content and financial resources), management and further development of the funding-program.

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

Young clinical researchers are thought to occupy in the future staff positions in the various services of a university hospital. However, recruitment of staff physicians is a problem for most university hospitals. Therefore, developing attractive employment and career opportunities for such young clinical researchers should be considered by the university hospitals as a win-win initiative. This implies a bottom-up process that starts in the medical services (identification of potential candidates), continues with the establishment of a dual path allowing the clinical specialization in parallel with academic activities (chief of service, along with the medical and academic authorities), and ends with a formal and personalized career plan, and a specific mentoring. This also implies that protected time can be provided by the university hospitals and financial support for the academic salary guaranteed by sources that may include the hospitals formation budgets, the universities, the SNF as well as private foundations.

Through WP 5, Medical Faculties and University Hospitals will jointly elaborate a concept, how attractive employment and career opportunities for young clinical researchers can be put into place, taking into account the respective existing recommendations9-12.

Milestones:

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<tr>
<td>1 (06/2018)</td>
<td>A joint concept on research-friendly conditions of employment and career opportunities at University Hospitals is elaborated</td>
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Responsibility: The association “University Medicine Switzerland” will be responsible for the elaboration of a concept for improving the conditions of employment and career opportunities at University Hospitals (confirmation of the UMS-Board of directors pending).

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10 Empfehlungen für gendergerechte akademische Karrierewege. Akademien der Wissenschaften Schweiz (2016)
11 Nachwuchs für die Klinische Forschung. Gemeinsamer Bericht der Schweizerischen Akademie der Medizinischen Wissenschaften und des Bundesamts für Gesundheit (2014)
12 Wissenschaftskultur und Nachwuchsförderung in der Akademischen Medizin. Positionspapier der Schweizerischen Akademie der Medizinischen Wissenschaften (will be published in summer 2016)
Next steps and future outlook

The proposed time frame for elaboration and preparation of the planned measures is 2016-2018. The SCTO will be in charge of the overall management, i.e. advancements as well as difficulties and obstacles are reported, and completed WP are delivered to the executive office of the SCTO. If considered necessary, the FOPH may convene additional meetings of the taskforce (or other formations). The target date for put into place the national framework structure for clinical research education is the beginning of the fall semester 2018.

A pilot period of three years (09/2018-09/2021) will be closely accompanied and followed by an evaluation. The FOPH will coordinate this evaluation and provide the required financial means, with reservation of the budget decision of Federal Council and parliament. The evaluation report will provide the basis for adjustment of the framework structure and its portfolio, for preparation of a subsequent funding solution of the starter-grant program and for consideration of new and/or follow-up activities.

Figure 2: Roadmap illustration
IV. Attachment

Recommendations of the 2014 SAMS/FOPH-report

*Level education*: Research-oriented medical students should be identified, encouraged and introduced to the field of clinical research as early as possible.

**Measures:**
- Launch of events / measures to identify and motivate research-oriented students;
- Offering of courses in order to gain qualifications / track record in clinical research already during the Master programme;
- Courses in clinical research are offered within the framework of the MD-PhD-programs.

*Level training/specialization*: Research-oriented doctors in specialist medical training should have the opportunity to acquire professional qualification and competences within the field of clinical research.

**Measures:**
- The specifications concerning research competences of doctors (in SCLO, MedBG and WBO) are implemented accordingly;
- 1 year of patient-oriented research is credited in all specialist medical trainings;
- Bundling/grouping of existing training opportunities in the field of clinical research.

*Level establishment*: In hospitals, research-friendly structures / conditions of employment and career opportunities for clinical researchers are needed.

**Measures:**
- Provision of jobs for assistant doctors and chief consultants with contractually stipulated percentage of research-time;
- Definite launch of the call "Protected Time" by the SNSF;
- Creation of (additional) Assistant Professorships with min. 50% research-time.

Contributors to the Roadmap

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- Curafutura, Interpharma, vips, scienceindustries,
- Intergenerika, FASMED, IG Schweizer Pharma KMU, Swiss Biotech Association, swissuniversities