



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

## Commented consultation report

The consultation process was carried out in three steps:

1. The first draft of the Roadmap<sup>1</sup> was elaborated with a wide range of experts forming a task-force under the lead of the Federal Office of Public Health. It was subsequently presented at the Round Table meeting concerning the Federal Council's Masterplan to strengthen Biomedical Research and Technology in Switzerland at May 2<sup>nd</sup> 2016 in presence of Federal Councillor Alain Berset. The participating stakeholders directly discussed questions, problems and suggestions with the representatives of the Federal Department of Home Affairs and the Federal Office of Public Health.
2. Institutions and organisations with a direct or indirect link to clinical research<sup>2</sup> were invited to give their feedback to the Roadmap draft.
3. Public consultation process: the Roadmap draft was presented to the research community during the 7th SCTO-Symposium held on June 16, 2016 in Lausanne and discussed during the panel debate. All participants were furthermore invited to submit their written feedback to the FOPH.

In total, we received 23 written statements until July 31, 2016.

The Roadmap-draft has been very positively received. Hereinafter, a summary of the written and oral feedback is provided, citing the key messages concerning general aspects, the individual work packages (WP) as well as financial aspects. *Comments in italic* indicate, how the respective aspects will be taken into account within the overall concept of building up the future generation of clinical researchers. The detailed planning, elaboration and management of the WP is under the responsibility of the concerned partners. Therefore, specific details concerning the WP mentioned during the consultation process were not incorporated into the final version of the Roadmap. However, this consultation report shall be used as a complementary basis for discussion in the respective working groups.

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<sup>1</sup> The final draft of the Roadmap was released in April 2016, as version V16. It is online available under: [https://www.scto.ch/dam/jcr:8f1993d0-e1c4-4f34-9487-54ba11d08ecd/Roadmap-draft\\_V16.pdf](https://www.scto.ch/dam/jcr:8f1993d0-e1c4-4f34-9487-54ba11d08ecd/Roadmap-draft_V16.pdf)

<sup>2</sup> The following institutions and organisations were contacted: SERI, Health Policy Directorate FOPH, SNSF, Swissethics, SCTO, Oncosuisse/SAKK, SAMS, Conference of Cantonal Health Directors, University Medicine Switzerland, FMH, SIWF, SGPM, ECPM, SwAPP, SPO Patientenschutz, Dachverband Schweizerischer Patientenstellen, santésuisse, Curafutura, Interpharma, vips, scienceindustries, Intergenerika, FASMED, IG Schweizer Pharma KMU, Swiss Biotech Association, swissuniversities.

## 1. General aspects

### 1.1. Scope of the Roadmap

Research promotion within a specialised field is closely linked to the overall structure of the respective education program. Depending on the education structure, different opportunities for placing the accent on the scientific aspects and for early sensitisation for research are given. The Roadmap should therefore take into account considerations concerning a possible restructuring of the medical curricula in Switzerland (e.g. by the introduction of medical schools, as suggested in the Loprieno-Report of the SERI).

*The taskforce agrees that a restructuring of the medical curricula as it was proposed in the Loprieno-Report could have positive effects for the promotion of clinical research. However, with regard to a prompt start of the activities and a timely successful outcome, the aim of the Roadmap is to optimise currently existing structures. A potential restructuring of the medical curriculum must be the content of a separate roadmap.*

### 1.2. Interprofessionality

Several feedbacks included the reference that clinical research is an interprofessional and interdisciplinary field. Not only medical doctors, but other medical professions (such as nurses, nursing scientists, medical informatics or technicians) as well as biologists, pharmacists, psychologists, biostatisticians or bioinformatics are involved in clinical research. Therefore, they should be included in the promotion strategy.

*The taskforce is aware that the clinical research workforce is based on many different professions. The decision to focus on the promotion of medical doctors (as a start) was due to the origin of the mandate (the initial mandate came from the consortium "Future Medical Education"). One of the major hurdles of this career path is combining medical specialisation training and clinical research. However, the idea is to offer newly established services in the future also to other professions and disciplines (as far as applicable).*

### 1.3. Cooperation with / inclusion of partners

The promotion of clinical research has a direct impact on the affected hospitals and further training centres. Moreover, the WP might affect the continuing education ordinance and the continuing education programs of the specialist societies. Therefore, the Swiss Institute for continuing and further education (SIWF-ISFM) and the specialist societies should be fully and effectively involved in the national Roadmap.

*A close collaboration with the SIWF and the specialist societies with regard to an exchange of experience and coordination/harmonisation of activities is planned (and already mentioned in the Roadmap: Figure 2, WP2, evaluation phase). In order to emphasise this intention, the planned close collaboration with SIWF and specialist societies is mentioned also in the definite Roadmap text (on page 8).*

### 1.4. Delimitation to other education qualifications and international compatibility

Education and training requirements concerning the individual function within a study-team are already defined, and swissethics is competent for the respective recognition of research ethic and GCP courses. The training opportunities addressed in the Roadmap should take into account these requirements. Moreover, the delimitation of clinical research trainings to further qualifications (e.g. in the field of pharmaceutical development or pharmaceutical medicine) should be clearly communicated, in order to not confuse young talents. Since medical doctors move across borders (being motivated by higher salaries, better

working or research conditions, new professional experience, as well as training and career opportunities), it is important to also take into account international standards and framework conditions for the training in clinical research.

*The respective competent partners (such as swissethics, SwAPP, SGPM etc.) will be involved in the further elaboration and implementation of the WP. The responsible partners for the WP are in contact with the respective European Networks and a maximal degree of compatibility with international standards and expectations is aspired.*

### 1.5. Range of education topics

Aside from the actual contents in the field of clinical research, the following related subjects were proposed to be taken into account within the overall concept of building up the future generation of clinical researchers.

- Ethical, legal and social aspects
- The connection to basic research (correct research question) as well as to the relevance of application in and the transferability into the clinic
- The increasing importance of integrated and translational research (due to the fact that the line between basic and clinical research is increasingly difficult to draw)
- Big Data, Biobanks
- Secondary usage of care data for clinical research

*The taskforce as well as the responsible partners of WP 2 and 3 will encourage course providers to take these proposals into account.*

## 2. Individual Work packages of the Roadmap

### 2.1. Work package 1: Collaboration with local MD-PhD Graduate Schools

- Excellence in basic research requires a different set of skills than in clinical research – this is why some locations decided to establish new PhD-programs in clinical science, independent of the existing MD-PhD-programs. For the latter, this could imply (or already implied) that the creation of new structures within their programs is necessary.
- A PhD-degree (e.g. in basic sciences) is conferred for an excellent individual and independent research performance. In clinical research teams, the individual contribution of research performance can be more difficult to evaluate than in “single disciplines”. New assessment strategies and more complex regulations might be necessary to cope with this problem. However, it can certainly not be the objective to establish a “PhD-light”.

### 2.2. Work package 2: Minimum standards for competencies in clinical research

- The Minimum Standards for medical doctors will presumably be similar to those of the PhD-programs in clinical science. Therefore, a close collaboration between the responsibly partners of WP 1 and 2 is expedient.
- Minimum Standards should have a highly practical approach. It could therefore make sense to include active clinical researchers (from academy and industry) into the elaboration team of WP 2.
- The definition of minimum standards should be a dynamic approach rather than a “snapshot”, i.e. periodic evaluation and adaptation would be inevitable.

- The broad definition of clinical research, as it is referenced in footnote 2 of the Roadmap, will probably make it difficult to define minimum standards for competencies in clinical research. Therefore, minimal standards should only be defined for the field of clinical studies (with human subjects).
- Set these minimal standards to be transferrable between universities, as a substantial number of MD travel between Swiss Universities (and abroad), so one course/competence acquired somewhere should be recognized and credited accordingly in other institutions.
- The online list of courses should make its offer widely known, something similar to the SPSS+ newsletter and other communication means (e.g. social media etc.).

### 2.3. Work package 3: Swiss Clinical Research Education Centre

- Interdisciplinary collaborations (e.g. between clinical disciplines, public health, nursing sciences, etc.) are important for the creation of local exchange- and activity-platforms. Collaboration between those platforms and the SCREC are necessary to make clinical research more attractive.
- Since methods and competences of clinical research are similar to those of public health (PH) research, a collaboration between already existing regional and national PH programs, such as the SSPH+ or the MPH-program of the universities of Basel, Bern and Zurich should be pursued.
- A structured program for clinical research is most desirable, but it would be contra productive, if the completion of such a program would become a mandatory requirement for clinical research activities in Switzerland.
- Because this is a virtual school, to reach the maximal audience, the school could use conference calls and online course technologies when applicable, so that young clinical scientists from across CH will be able to virtually attend the courses and coordinate this with their clinical duties. It is easier to attend a virtual course of 3-4h on half a day (and clinic during the rest of the day) than travelling for 2 hours one-way and return which would require the whole day and more travel expenses.
- For the coordination of the WP and for the maintenance of the SCREC, a new position at the SCTO should be created and filled with someone, who brings knowledge and background in medical education and research matters, in order to be able to deliver qualified advice to research-oriented doctors, and to contribute to the further development of the interdisciplinary training possibilities and the exchange of experiences.
- A national coordination seems appropriate. However, the SCREC should not develop into a bloated bureaucratic structure, but be kept as lean as possible. Services that are already provided by the Universities (e.g. soft-skills courses, mentoring programs) should not be part of the SCREC-portfolio. The SCREC should have only coordination function, the universities as well as the SIWF should have the lead of the services.
- The Swiss Group for Clinical Cancer Research (SAKK) should be involved in WP3.
- In addition to the virtual school SCREC, the creation of a physical education centre should be considered.

### 2.4. Work package 4: Funding program for physicians in clinical research (starter-grants)

- Experience of research promotion programs for young talents show that it is rather difficult to properly evaluate the academic performance and the potential of young candidates. It is necessary that WP4 precisely defines the target-group as well as type

and duration of promotion. Synergies with existing measures should be taken into account. Moreover, the program must take into account the principle of equal opportunities.

- In how far money of the private industry should/could be used for the promotion program (as opposed to money from private foundations) should be a matter of debate (keywords: conflict of interest, return on investment, reputation risk).
- Experience with promotion programs in clinical research shows that the linkage of and the networking between research partners plays a central role. An additional task of the national promotion program should therefore be the specific interconnection of the involved institutions. Moreover, it seems important that the responsibilities for the individual researcher (in the sense of supervision/mentoring) should be clearly defined within the network and assigned to one mentor/institution.

## 2.5. Work package 5: Research-friendly conditions of employment and career opportunities

- *Several stakeholders mentioned, that WP5 is the most important WP and the Roadmap will only be effective, if WP5 will be successfully implemented. Since the Roadmap text should reflect this consideration, a corresponding phrase was included in the final version of the Roadmap, page 7.*
- Mentoring and discovering new talents is key. Dual mentoring could be interesting (one with a strong research link and the other one with a stronger clinical link) to find the right balance.
- Appropriate work environment for young parents with maternity / parental leaves or partial time conditions.
- A research-friendly work environment is essential for the development of a successful career. A “Dual path specialization“, however, entails the risk that both tracks are slightly neglected resulting in deficits in both disciplines at the end.
- The Swiss Academy of Medical Sciences should also be engaged in this WP.
- It is important that also non-University-Hospitals develop research-friendly conditions of employment and career opportunities, since many of the research projects in Oncology are carried out at Cantonal or Regional Hospitals.
- It has to be taken into account that the motivation for the engagement in clinical research is and always will be the personal career planning. At the moment, the revenue in clinical research is smaller than in other research fields. It is, therefore, particularly important to support and promote clinical researchers in their career aspirations. However, there will be always “drop-outs” from clinical research, who shift their main activities back to routine care.
- For clinical researchers, two “levels” should be distinguished: researchers, who want to carry out their own projects and those, who only wish to partly participate (e.g. by bringing in their patients into clinical studies). Both levels should be established in as many hospitals as possible, because the inclusion of clinical studies into the daily care routine is an essential factor not only for the promotion of clinical research but also for the promotion of scientific aspects in routine care. The conduct of clinical studies is accredited for most quality certifications.

### 3. Financial aspects

- The promotion of clinical research in education and training must be seen within the context of the challenges induced by the shortage of doctors and the security of service provision. During the time, which doctors invest in research and research training, they are not available for routine care. These challenges - in human and financial terms - must be recognised.
- The effective costs for clinical education as well as research and development at the university hospitals are largely unknown. An additional WP could be considered, in order to generate data of sufficient quality to be able to provide detailed information concerning those costs.
- A stronger commitment of the federal council in form of a financial engagement (e.g. through earmarked subsidies) would also be desirable, in order to effectively realise the Roadmap endeavour.
- The implementation of the measures and activities envisaged in the Roadmap is dependent on specific investments. Altogether, the future of clinical research in Switzerland is depending on the current development of the question of financing of hospitals. Presently possible financing mechanisms should be better exploited and new financing possibilities should be opened.

*Since there is no federal funding available for the implementation of the WP-activities, the involved organisations bear the costs for the implementation of the measures and activities envisaged in the Roadmap. The objectives of the roadmap were established in close collaboration with all directly concerned organisations. Therefore, objectives are in line with the strategies of these organisations and they are in general prepared to allocate the required budget to the planned activities. However depending on the single organisation's financial situation, adaptations may be required and/or further funding sources need to be identified. Since the Roadmap text should reflect this consideration, a corresponding paragraph (Financial aspects) was included in the final version of the Roadmap, page 8.*