SAMW ASSM
Schweizerische Akademie der Medizinischen Wissenschaften
Académie Suisse des Sciences Médicales
Accademia Svizzera delle Scienze Mediche
Swiss Academy of Medical Sciences

Coordination Platform Clinical Research: Annual Report 2022

1. Context

The national Coordination Platform Clinical Research (CPCR) was set up in December 2021 by the SAMS, on behalf of the SERI[1], to strengthen the institutional dialogue and the coordination between the public stakeholders of clinical research. Its mission is to help define concerted priority action areas in line with the vision presented in the White Paper Clinical Research[2] and to allow for a clear and efficient distribution of tasks and responsibilities. The CPCR is further responsible to formulate recommendations to decision-making bodies or to the SERI.

The need for a stronger coordination was a central message of the White Paper. Indeed, while the paper acknowledged the improvements in clinical research in Switzerland in the past twenty years, thanks to public investments in several initiatives, research infrastructures and support instruments, it also pointed out that his had led to a fragmentation of activities and to potential redundancies, with deficits remaining. Seven goals, accompanied by a roadmap and recommendations, were formulated to improve the quality and impact of clinical research.

The first recommendation was the creation of a national platform to reinforce the cooperation and efficient use of ressources between the key academic stakeholders of clinical research. This platform would also be in charge of defining the framework conditions for the implementation of the measures outlined in the White Paper. The experts group considered that none of the existing structures, which all had a specific focus, was set so as to serve as a national, single point of contact where stakeholders of the entire spectrum of clinical research, including public health, could discuss and coordinate their activities.

This report presents an overview of the activities of the CPCR since its launch in December 2021.

2. Composition and setting up

As stated in its mandate, it was decided to keep the size of the CPCR small during its build-up phase (2021-2024) to ensure an efficient functioning. It currently consists of 13 members with voting right, who are representatives of the key academic organizations and stakeholder groups involved in the discourse on clinical research. Further stakeholders and experts are invited to participate in CPCR meetings as guests. Prof. Henri Bounameaux, President of the SAMS, chairs the platform. The names of the members and guests are provided in chapter 5.

a) **Members:** early career researcher representative, ETH Domain, patient representative, SAMS, Swiss Biobanking Platform (SBP), Swiss Clinical Trial Organisation (SCTO), Swiss Group for Clinical Cancer Research (SAKK), Swiss National Science Foundation (SNSF), Swiss Personalized Health Network (SPHN), Swiss School of Public Health (SSPH+), swissuniversities (2 members: 1 representative from universities, 1 representative from universities of applied sciences in health research), unimedsuisse.

b) **Permanent guest:** SERI (mandating federal instance), and as of 2023, FOPH.

c) **Ad-hoc guests:** depending on the issues treated, e.g., swissethics, Swissmedic, Schweizerisches Institut für ärztliche Weiter- und Fortbildung (SIWF/ISFM), industry

[1] SERI mandate to the SAMS «Aufbau und Betrieb einer nationalen Koordinationsplattform für klinische Forschung (Koordinationsplattform Klinische Forschung, KKF)», 01.07.2021 – 31.12.2024.

[2] White Paper: Clinical Research, SAMS (2021), Swiss Academies Communications 16 (4). This strategic paper was elaborated by a group of experts on behalf of SERI, with the task to analyze the state of clinical research in Switzerland and to develop a consolidated vision for its future. The recommendations of the White Paper were taken into account for the elaboration of the federal Masterplan Biomedicine 2022-2026.

representatives, individual experts.

During the summer 2021, the SAMS invited the organizations listed under 2.a) to delegate a high-level representative in the CPCR. The Swiss Young Academy was contacted to recommend an early career researcher with a fitting profile. On the advice of the White Paper experts group, the patient representative was recruited via an open call (more information under 3.1).

The CPCR was constituted with an initial meeting on 1st December 2021, in which its rules of procedure were discussed and approved. The tasks of the CPCR and the priority topics to address during the first work period were discussed and agreed upon.

3. Review of activities since the launch of the platform

The activities of the CPCR are derived from the White Paper. The initial focus was thus set on the goals and measures explicitely attributed to the CPCR in the White Paper roadmap. The following goals were given a high priority and, in view of the resources available, defined as those to be addressed first: (1) reduction of redundancies through a clear distribution of tasks and responsibilities (White Paper goal 1, measure a), (2) harmonization of ethics approval processes at the national level (goal 7, measure a), and (3) national coordination of career support in clinical research (goal 1, measure a) and goal 6).

The handling of the two remaining goals attributed to the CPCR in the White Paper were postponed: (4) set up of public campaigns to foster participation in clinical research» (goal 2, measure a), considered as very relevant but for which more resources than currently available would be required, and (5) development of a label for public institutions involved in clinical research (goals 1 and 3), which the CPCR postponed for further discussion. Finally, regarding the activities related to the political implications of the White Paper, the CPCR decided to first start to work on the identified issues and to approach politicians with concerted, concrete requests for support at a later time point.

3.1. Recruitment of patient representatives

The call for a patient representative, open to any interested person fitting the profile defined by the CPCR, was launched early 2022 and disseminated via the SAMS and SCTO-PPI Hub communication channels. It was also sent directly to patient organizations. A subcommittee of the CPCR was in charge of the selection procedure. Two persons with experience as patient in a clinical research setting, a broad interest in medical topics and a strong motivation to bring the voice of patients in a national, institutional context were recruited, as main and deputy patient representatives. Other applicants with interesting profiles and expertise agreed to be contacted again if a patient sounding board was needed in the future.

3.2. Reduction of redundancies through a clear distribution of tasks and responsibilities

To tackle the first goal of a better alignement of efforts on concerted priorities and of a reduction of redundancies through a clear distribution of tasks and responsibilities, the service level agreements of the CPCR members with the SERI, or with their mandating instance, and their strategic priorities for the period 2021-2024 were reviewed to identify potential overlaps.

The focus was first set on CPCR members providing infrastructures, resources and services for the clinical research community (SAKK, SBP, SCTO, SPHN). Core activities and strategic objectives were compared and regrouped in thematic categories (data sharing and reuse, sample sharing, methodological support of clinical studies, transversal thematic platforms, patient involvement, support of early career researchers, partnership with industry, setting of concerted national priorities). The areas in which potential redundancies between the organizations had been identified served as a first discussion basis. The discussion was then deepened by looking at the activities and services offered, starting with the topic of data sharing and reuse, thanks to an analysis provided by the SPHN. The discussion of the other topics will

be pursued. The aim of these successive discussion rounds is to find a consensus among CPCR members on the areas in which a clearer distribution of tasks is necessary and to ensure that their activities are complementary. This consensus should then be reflected in the wording of the strategic priorities of each organization.

As a next step, the results of the analysis will be used to develop a visual map of the services provided by each organization, in particular those provided to researchers. The map, which will be published online, should help to make the division of tasks more transparent, both for CPCR members and for the research community.

3.3. National harmonization of ethics approval and other regulatory processes

A CPCR working group, led by the SCTO, was tasked to address the second priority aim regarding the harmonization of ethics approval processes at the national level. The working group suggested to include the identification of other regulatory pain points in its analysis and to bring the issues to concerned stakeholders. Using the Human Research Act and its ordinances for different types of studies as a framework, the working group started to identify the major regulatory issues where procedures could be simplified or harmonized. The experience of researchers at the front will also be included in the analysis.

As a next step, the identified issues will be prioritized by the CPCR, and proposals for simplification or harmonization will be discussed with the responsible authorities, among which swissethics, Swissmedic and the FOPH at the national level. Indeed, the FOPH is in charge of the ongoing revision of the HRA ordinances, which results from the evaluation of the HRA and which pursues the same objective of further harmonizing the procedures of cantonal ethics committees (see Masterplan Biomedicine 2022-2026 for more details).

3.4. National coordination of career support

To start and address the last priority topic for this first year of activity of the CPCR, namely the improvement of the national coordination of education and career support in clinical research, a working group composed of a few CPCR members was set up. In alignment with the recommendations of the White Paper, the focus was first put on the PhD level. A mapping of all clinical (MD-) PhD programs in Switzerland, with an analysis of their curricula and a comparison with well established international PhD programs in Northern Europe, was made. The results will serve as basis to draft national minimal standards for clinical PhD programs for various researchers profiles, in particular for physicians and health professionals.

As a next step, the mapping will be completed by an assessment of the various clinical PhD models, which either focus on research or allow to combine research with parallel clinical training. The minimal standards will be discussed with involved institutions, with the aim of a broad endorsement. In a second phase, a proposal for adequate funding instruments for clinical PhD students will be elaborated.

4. Secretariat and finances

The SAMS is in charge of the secretariat of the CPCR, which is currently chaired by the SAMS President. During the ERI period 2021-2024, the personal and financial resources of the CPCR are part of the core funding of the SAMS by the Confederation. Approximately 25% of a scientific officer position could be dedicated to CPCR activities during its first year of operation.

The secretariat is responsible for the preparation of the agenda and of meetings with the chairperson. It supports the CPCR as plenary organ, and, within possibilities, the CPCR working groups, in their analysis and in the elaboration of recommendations and publications. The secretariat is also in charge of informing the CPCR members, the SERI and further relevant partners about the platform activities. So far, these communication activities were limited since the available resources were primarily invested in the support of the CPCR priority work packages.

5. Composition of the CPCR

Prof. Henri Bounameaux, Satigny, SAMS (Chair)
Prof. Claudio Bassetti, Bern, swissuniversities – universities
Christine Bienvenu, Romanel-sur-Morges, patient representative
Dr. Mey Boukenna, Bern, early career researcher
Dr. Christine Currat, Lausanne, Swiss Biobanking Platform
Prof. Mirjam Christ-Crain, Basel, Swiss National Science Foundation
Prof. Urs Frey, Basel, Swiss Personalized Health Network
Prof. Andreas Gerber-Grote, Winterthur, swissuniversities – universities of applied sciences
Prof. Christiane Pauli-Magnus, Basel, Swiss Clinical Trial Organisation
Prof. Arnaud Perrier, Genève, unimedsuisse
Prof. Miklos Pless, Winterthur, Swiss Group for Clinical Cancer Research (since 01.01.2022)
Prof. Nicole Probst-Hensch, Basel, Swiss School of Public Health
Dr. Nicole Schaad, Bern, State Secretariat for Education, Research and Innovation (guest)
Dr. Myriam Tapernoux, Bern, SAMS (ex officio)
Dr. Sarah Vermij, Bern, SAMS (ex officio, until 30.06.2022)
Prof. Roger von Moos, Chur, Swiss Group for Clinical Cancer Research (until 31.12.2021)
Prof. Bernd Wollscheid, Zürich, ETH-Domain
Jennifer Woods, Basel, deputy patient representative

Brigitte Meier, Bern, Federal Office of Public Health (new guest, as of 01.01.2023)

Authors:

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