

## Coordination Platform Clinical Research: Brief Activity Report (12.2021–12.2024)

### 1. Initial objectives of the CPR

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

The platform was created in response to the recognition among most stakeholders that the increasingly fragmented academic landscape of clinical and health research lacked an overall vision and a central lever to ensure consistency in strategic priorities between institutions. Indeed, while many improvements have taken place thanks to public investments in several initiatives, research infrastructures and support instruments over the past years, the fragmentation is an obstacle to achieving optimal results in terms of research quality and impact.

The primary objective of the coordination platform is to provide a legitimate space to support dialogue between all key academic stakeholders in patient-oriented research in the broadest sense – including public health research and data-based research – active at the national level.

The SERI mandate to the SAMS was given for a «build-up» phase, with an option for continuation if the platform was considered useful. This report presents a brief review of the activities of the CPCR from December 2021 to December 2024, and an outlook in view of the 2025–2028 ERI period.

### 2. From the White Paper Clinical Research to the CPR

The experts and stakeholders involved in drafting the White Paper Clinical Research (the work took place from 2020 to mid-2021) identified the following areas in which central coordination and top-down levers for action are lacking, i.e. where no single organization has a clear leadership role at the national level and where improvements would have the greatest impact:

- 1) Strengthening patient and public involvement at the national level – proposed measure: launch of joint communication campaigns
- 2) Collaboration between hospitals and universities – need for clear agreements on the use of research infrastructure and personnel costs
- 3) Elaboration and implementation of harmonized standards for the exchange of clinical data – definition of binding standards, aligned with international norms, by a national reference organization
- 4) Training and career support for researchers, particularly at the beginning of their careers – funding for MD-PhD and clinical PhD students, increase in the number of clinician-researcher positions in hospitals

---

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

<sup>2</sup> [White Paper: Clinical Research, SAMS \(2021\), Swiss Academies Communications 16 \(4\).](#)

- 5) Harmonization at the national level of ethical and regulatory processes for multicentric research projects – centralized submission and approval of ethical authorizations; harmonized electronic submission, processing, and approval of informed consent forms.

By strengthening a culture of collaboration, the CPRC should enable institutions and initiatives to define joint priorities on which to align their own strategies and activities. The platform also aims to facilitate the development of joint recommendations for the SERI or other decision-making bodies in order to improve the framework conditions for patient-oriented research.

### **3. Composition and setting-up**

In line with its mandate, the size of the CPRC has been deliberately limited during its initial phase to ensure an efficient functioning. However, its composition must be able to adapt to changes in the landscape in order to best fulfill its mission. During the build-up phase, it consisted of 13 members representing the main academic organizations active at the national level and the main stakeholder groups involved in patient-oriented research. The SERI and the FOPH participate as permanent guests. The president of the SAMS chairs the platform.

#### **Members of the CPRC**

- Early career researchers representative
- ETH Domain
- Patient representatives
- SAMS (Chair and secretariat)
- Swiss Biobanking Platform (SBP)
- Swiss Clinical Trial Organization (SCTO)
- Swiss Group for Clinical Cancer Research (SAKK)
- Swiss National Science Foundation (SNSF)
- Swiss Personalized Health Network (SPHN-DCC)
- Swiss School of Public Health (SSPH+)
- swissuniversities (1 representative from universities, 1 representative from universities of applied sciences in health research)
- unimeduisse

#### **Permanent guests**

- SERI (mandating instance)
- FOPH

The names of the members and guests are listed in Chapter 7.

The CPRC was established at its first meeting on December 1, 2021, during which its rules of procedure were discussed and approved. The tasks of the CPRC and the priority topics to be addressed during the first working period were discussed and approved.

### **4. Review of activities since the launch of the platform**

The platform's activities during its first period of activity were derived from the White Paper. Among the many ambitious objectives assigned to the CPRC, priority has been given to three topics in view of the resources available: 1) reduction of redundancies through a clear division of tasks and responsibilities (aim 1, measure a) of the White Paper), 2) harmonization of ethical approval processes at the national level (aim 7, measure a), and 3) national coordination of career support in clinical research (aim 1, measure a) and aim 6).

The two remaining objectives assigned to the CPRC in the White Paper have been postponed: the launch of joint communication campaigns to strengthen the involvement of patients and the public in clinical research (aim 2, measure a), which was considered highly relevant but would require more resources than currently available, and the development of a label for academic institutions involved in clinical research (aims 1 and 3), which the CPRC postponed for further discussion. Finally, with regard to activities related to the policy implications of the White Paper,

the CPRC decided to start working on the issues identified and to approach policy makers with concerted and concrete requests for support at a later stage.

#### **4.1. Reduction of redundancies through a clear division of tasks and responsibilities**

To tackle the first aim of a better alignment 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 CPRC 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 set initially on CPRC members that provide infrastructure, resources, and services for the processing of clinical data and samples for research (SAKK, SBP, SCTO, SPHN-DCC). The areas in which potential redundancies between organizations had been identified served as a first basis for discussion in the CPRC plenum. The plenum wanted the discussion to be deepened by examining the concrete activities and services offered.

This preliminary analysis confirmed that there were indeed probable overlaps – at least some ambiguities – in the services provided and how organizations described their field of responsibilities and their activities. This was visible in several thematic areas, among which: data access, sharing, reuse and governance; sample sharing and governance; methodological support for clinical researchers; training offers.

Importantly, the analysis also suggested that there was a strong potential for collaboration and through a clarification of the roles of the organizations, depending on the context in which they provide their services, an opportunity to improve the use of resources and make the service provision landscape more transparent and legible for users.

A working group, co-led by SBP, was set up and produced a joint, structured list of the services offered by the four service providers. A visual tool (a dynamic map based on this harmonized list of services) should facilitate discussion and consensus-building among CPRC members in areas where a clearer division of tasks is needed to ensure that their activities complement each other. This consensus should then be reflected in the formulation of each organization's strategic priorities and in their communication towards the community.

A first prototype of the «map of services» was presented to the CPRC. The plenum requested that the services be better differentiated from one another. The working group refined the harmonized categorization of services as much as possible, based on the information provided by its members and in a spirit of consensus. With the support of visualization experts from SBP, a new prototype of a dynamic map was developed based on keywords extracted from the service descriptions. On this new map, which was discussed and approved by the CPRC plenum, each service was positioned according to its proximity to the main activities of its organization. The map thus highlights areas of activity at the interface between organizations that may require better coordination.

The CPRC plenum asked the working group to further improve the common vocabulary used to describe services and that new information that some service providers wished to make available about their own services be taken into account in a future version of the tool. These new elements were implemented in a new iteration of the prototype, with improved search function. This prototype was presented to and validated by the CPRC plenum. The dynamic «map of organizations», with its joint list of services, described with a common vocabulary, was transmitted to SERI in October 2024 to serve as supporting material in view of the elaboration of the SLA 2025-2028.

The work is continuing to adapt the content of the «map of organizations», focused on the interfaces between the providers, into a «map of services» for researchers and other interested users, allowing them to easily identify which services are available and whom to contact depending on their needs. The development of this new prototype and its testing is planned in the first half of 2025. The final tool should be ready to be published on the websites of all organizations providing the services in the second half of 2025.

## **4.2. National harmonization of ethics approval and other regulatory processes**

A CPR working group, led by the SCTO, was tasked with addressing the second priority objective concerning the harmonization of ethics approval processes at the national level. Its mandate was to identify which pragmatic elements could be improved and simplified through better cooperation between stakeholders, without requiring changes in the Human Research Act (HRA). The working group suggested including in its analysis the identification of other problematic points related to the regulations and bringing these issues to the attention of the relevant authorities. Using the HRA and its ordinances as a framework, the working group identified the main regulatory issues for which procedures could be simplified or harmonized. Practical experience was also taken into account in the analysis through the CTUs.

The working group produced an initial list of issues. The issues identified were discussed and prioritized by the CPR, which asked the working group to develop concrete proposals for simplification or harmonization. These proposals were validated by the plenum and discussed with the responsible authorities – swissethics and the FOPH – in the autumn 2023.

The main take-aways were the following:

### **>> The submission requirements for multi-centric projects should be harmonized**

Different interpretation of the law by local ethics committees (EC), diverging practices regarding review of registries, different requirements regarding use of data collected with general consent (GC) or regarding anonymization are all hindering research. While some improvements were expected thanks to the revision of the HRA ordinance entered into force in the autumn 2024 which empowers swissethics vis-à-vis the local EC, a stronger harmonization of EC practices should be defined in the law (HRA). The consultation of each EC, in addition to the lead EC, needs to be simplified and limited in scope in the upcoming revision of the HRA.

### **>> EC authorization processes regarding use and reuse of health data should be harmonized**

EC should use the reference guidance documents of a single responsible national organization (currently different guidance documents from the SCTO RA platform and from SPHN-DCC co-exist). And here too, a stronger harmonization of EC practices should be defined in the revision of the HRA.

### **>> Reuse of health data for research should be facilitated**

Other models for the general consent (GC), such as an opt out rather than an opt in principle, should be discussed in the context of the revision of the HRA.

The recommendations of the CPR will be integrated in the discussions around the upcoming revision of the HRA planned to start in 2025.

## **4.3. National coordination of career support in clinical research**

A third working group was set up to address the improvement of national coordination of education and career support in clinical research. In line with the recommendations of the White Paper, the initial focus was on the doctoral level. A mapping of doctoral programs in clinical research (PhD and MD-PhD) in Switzerland was carried out, including an analysis of their curricula and a comparison with recognized international programs in Northern Europe. This landscape analysis was enriched by an evaluation of the various clinically oriented doctoral models that focus on research or allow for a combination of research and clinical training. To this end, interviews (focus groups) were conducted with doctoral students, doctoral program directors, thesis supervisors, and clinical department heads from university hospitals in various regions of Switzerland. The results of these interviews were presented and discussed by the CPR plenary.

On this basis, and taking into account the relevant European recommendations, the working group elaborated minimal standards for doctoral programs in clinical research primarily intended for physicians and healthcare professionals. The document was discussed and validated after refinement by the CPR plenum. These standards are designed to serve as a

common reference framework and tool to reflect on the skills to be acquired in a doctoral program (PhD or MD-PhD) in clinical research and health research. They could also form a common foundation for facilitating exchanges between doctoral programs and early-career researchers in clinical research throughout Switzerland.

After initial discussion, the minimal standards were formally adopted by the College of the Deans of Medical Faculties (Collège des Doyens). They will be submitted to the Specialized Conference on Health of Universities of Applied Sciences for adoption by all relevant institutions. The dissemination of the minimal standards and the publication of the analysis were planned for the end of 2024. They had to be postponed for a lack of resources and will be published in 2025.

Future objectives could include developing a competency model that goes beyond defining a common curriculum, as well as considering new funding models to better support early-career clinical researchers. For this second objective, dialogue with swissuniversities, unimeduisse, and the SNSF will be necessary.

## **5. Secretariat and finances**

The SAMS is responsible for the secretariat of the CPR, which is currently chaired by the president of the SAMS. During the 2021-2024 ERI period, the CPR human and financial resources were part of the SAMS core funding, no dedicated financial support was allocated to the CPR by the Confederation. Approximately 25% of a scientific officer position could be allocated to CPR activities during the build-up phase of the platform.

The secretariat is responsible for preparing the agenda items and meetings with the Chair. It supports the CPR as a plenary body and, as far as possible, the CPR working groups in their analysis and in the elaboration of recommendations and publications, and coordinates their activities. The secretariat is also responsible for informing CPR members, SERI and other 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 CPR priority work packages.

## **6. Review and outlook for the ERI period 2025–2028**

The SERI mandate to the SAMS to set up a coordination platform with the key institutional stakeholders of academic clinical research active at the national level was given for a build-up phase until the end of 2024, with an option for continuation if the platform was considered useful. A consultation of the CPR members regarding the platform aims, composition, functioning, added-value and possible priority topics for the next period was conducted in the autumn 2024. The results were discussed in the CPR plenum in December 2024.

A large majority of the CPR members expressed a clear support for its objectives, saw added value in its work, and wished to pursue the efforts in a format allowing to realize joint projects based on common objectives, becoming more than a mere dialogue forum. They also expressed a wish for a clarification of the CPR purpose with a well-defined mandate, a strong institutional anchoring of its members, and a commitment to contribute to a common work program in a participative spirit.

To reach these ambitious goals, a sustained commitment of member institutions to the CPR goals is essential, and more resources must be invested to support the platform work and allow for a more efficient dissemination of the output of its work. The SAMS will bring these wishes to the SERI in view of the period 2025–2028.

At the end of its pilot period of activity, the CPR could established itself as a platform for institutional dialogue and consultation for all stakeholders in the field of patient-oriented research in the broadest sense, including clinical research and data-driven research. In this respect, it makes a unique contribution to the landscape. One of the platform main strengths is that it provides a framework to clarify the tasks and responsibilities of its members and allows

to work together to improve interinstitutional issues. In addition, while challenging, the CPRC is also beginning to play its role in bringing together stakeholders to elaborate coordinated recommendations to the authorities. This role should be strengthened in the next period to increase the impact of the CPRC work.

## **7. Current composition of the CPRC**

Prof. Henri Bounameaux, Satigny, SAMS (Chair)

Prof. Claudio Bassetti, Bern, swissuniversities – universities

Christine Bienvenu, Romanel-sur-Morges, patient partner

Dr. Christine Joye (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. Lauren Clack, Zurich, early-career researcher

Prof. Christiane Pauli-Magnus, Basel, Swiss Clinical Trial Organisation

Prof. Arnaud Perrier, Geneva, unimedsuisse

Prof. Miklos Pless, Winterthur, Swiss Group for Clinical Cancer Research

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. Salomé von Greyerz, Bern, Federal Office of Public Health (guest)

Prof. Christian Wolfrum, Zurich, ETH Domain

Jennifer Woods, Basel, patient partner

For the report:

Dr. Myriam Tapernoux, CPRC secretariat, April 2025