

Research Strategy of SAKK

Clinical research in the area of malignant neoplasia is a political mandate of the National Cancer Program for Switzerland 2011 - 2015 (National Strategy against Cancer 2014 – 2017). It optimizes the quality of treatment of patients with malignant tumors and ensures that the healthcare professionals involved, including junior academic staff, are suitably qualified.

Objectives of SAKK

SAKK implements academic clinical cancer research throughout Switzerland¹. SAKK is the leading organization for academic, clinical patient-oriented cancer research and is the most important sponsor/sponsor representative of such trials in Switzerland.

Framework Conditions

SAKK ensures that all members² in Switzerland that comply with the relevant regulations are able to participate in SAKK trials. SAKK may open trial centers in Switzerland and – if necessary for the achievement of objectives – abroad. Foreign centers meet the same criteria as Swiss centers.

SAKK is the owner of any data generated in those trials that it sponsors.

The international Advisory Board advises the commissions of SAKK.

SAKK meets the obligations towards the grant providers.

SAKK harmonizes the grant providers' objectives with the foci of research.

Research Objectives

1. Increasing the cure rate, life expectancy and quality of life of patients suffering from a malignant neoplasm.

Primary prevention of tumor diseases.

- 2. Secondary objectives:
 - a. Promoting multidisciplinarity of trials
 - b. Conducting therapy-optimizing trials, generally with long-term monitoring
 - c. Trials in cooperation with international academic research groups (cooperative groups), in which SAKK actively contributes to trial development
 - d. Access to new pharmaceuticals, immunotherapies, genetically modified organisms, medical devices, methods

Research Topics

 The SAKK Board determines the foci of research by appointing project groups (cf. SAKK Bylaws, see <u>organization chart</u>). The SAKK Board takes into account the potential of the research focus and possible future activities, including epidemiology, demography (summarized in the "Trial Portfolio") and the previous achievements of the project and working groups and sections.

The project groups define their research focus within the framework conditions set by the Board and formulate their areas of activity and priorities in a Trial Portfolio; they are counseled by the international advisors. The project groups generate the contents of the

¹ Reference to a future overall strategy of SAKK.

² Members are listed in the bylaws.

research projects of SAKK. They develop und update their research strategy according to the requirements and the strategy of the SAKK Board. The Board decides on the implementation of projects.

Selection of Research Projects

The SAKK Board assesses the research projects on the basis of research objectives, research methods and the available human and financial resources, and allocates these resources to the projects appropriately.

SAKK prioritizes according to the following criteria (in descending order):

- Clinical research (interventional trials) to improve the curative and palliative treatment of patients with cancer
- Translational research³
- Non-interventional clinical research. If the data are insufficient for an interventional trial, SAKK may create a data basis (e.g. Biobank, cohort study, registry study, retrospective data collection).
- Outcomes research⁴ and healthcare research.

The assessment of the research projects takes into account the research objectives.

Research Methods

The methods applied are suitable for answering the raised questions.⁵

Research Funds

SAKK may provide its own resources required for the development, implementation, analysis and publication of research projects⁶

Please note: This document is a translation from the German original. In case of discrepancies, the original German version of the Research Strategy is decisive.

- Trials on long-term and side effects of cancer therapies.
- Quality of Life studies, including as part of clinical trials
- Estimation of costs and cost effectiveness of various cancer therapies.

³ Translational research examines whether basic mechanisms found in biological scientific research in cell and other models are applicable to humans in respect of the development of possible treatment approaches.

In translational research projects, predictive and prognostic factors of a cancer of the blood and/or sample tissues of patients are examined and correlated with clinical data. The aim is to gain insights that can predict the use of a therapeutic intervention more precisely.

Outcomes research includes the following elements:

[•] Studies (or partial studies) that examine whether, and to what extent, the results of randomized clinical trials can be applied to the field of routine care.

⁵ Immediate consequence of the relation to the Declaration of Helsinki as well as ICH-GCP and HFG (*Human Research Law*); trials that do not lead to a useful result due to methodical weakness are excluded.

⁶ SAKK may delegate all or part of such functions to third parties, e.g. in the context of international collaboration with other research groups.