

Effingerstrasse 33 3008 Bern

SAKK Network Trial Award

Conditions of Participation and Evaluation Procedure

1. Definition

SAKK Network Trial Award - A Boost for Clinical Cancer Research

Clinical cancer research trials make a major contribution to the ongoing refinement and improvement of existing cancer treatments. In its capacity as a decentralized academic research institute, SAKK is launching a competition to fund a new SAKK clinical trial in medical oncology, hematology or a related field. Researchers within the SAKK network are encouraged to submit proposals for this competition, which offers a prize fund of MCHF 1.0.

2. Entry

2.1 Trial Proposals

Trial proposals will be considered if the following inclusion / exclusion criteria are met:

Inclusion criteria

- innovative
- pragmatic
- interventional
- SAKK acts as sponsor according to ICH-GCP
- trial runs in Switzerland only (if international, only Swiss part is funded)
- the Core Team of the research group has assessed and supported the idea
- the SAKK patient advisory board (PAB) was involved.

Exclusion criteria

- total budget exceeds MCHF 2.0
- investigational drug (IMP) and/or device not provided for by third party (e.g. pharmaceutical company or foundation)
- previously assessed by SAKK's Scientific Committee or the Directors' Committee.

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2.2 Trial Proposal Form

2.2.1 Content / Layout

- submission with SAKK Trial Proposal Form (TPF), available on the <u>SAKK Portal</u>. Portal access can be requested from the SAKK Competence Center (CC) via the group's liaison person
- must be written in English.

Contact the liaison person of the respective group as soon as possible to ensure **all** necessary documents are prepared.

2.3 Submission

Final proposals (including budget) must be submitted by e-mail bearing the subject line "SAKK Network Trial Award" to the Swiss Group for Clinical Cancer Research (SAKK) at proposals@sakk.ch no later than 18 April 2024.

3. Assessment

3.1 Assessment Criteria

Simple and pragmatic

- clinically relevant and clearly formulated research question and lean trial schedule
- limited number of secondary endpoints
- no purely translational research
- substantial involvement of the network and the CC.

Originality and innovation

- new treatment idea
- not a follow-up of an already running trial.

Appropriate methodology

assessed through SAKK CC protocol review committee (PRC) and Scientific Committee.

Patient oriented

- compatible with patients' needs (schedule of assessments, methods chosen)
- easy to understand lay summary.

Feasibility

- based on accrual and logistics
- incidence of a cancer will not be counted as negatively impacting feasibility.



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3.2 Evaluation & Selection

3.2.1 Evaluation

The evaluation of the projects will be done by the PRC (CSO, Medical Advisor, Statistician, CPD) at the CC and the Scientific Committee. The coordinating investigators will be invited to defend their projects.

3.2.2 Selection Part I: Directors' Committee

The first step of the selection process is conducted by the SAKK Directors' Committee (DC). It will consider the evaluations from the PRC and the Scientific Committee. The 5 best projects will be sent to the second selection step by end of May 2024.

3.2.3 Selection Part II: External Independent Jury

For the second step of the evaluation process, the SAKK Directors' Committee will appoint an independent external jury which will select the winner by mid-June 2024.

The external jury will rank the proposals based on predefined assessment criteria.

4. Financial Conditions

4.1 Prize Money

The MCHF 1.0 prize money can only be used to finance an SAKK trial (in full or in part).

4.2 Conditions for Payment

If the prize money is insufficient to fully finance the trial, the winner has 12 months from the date on which the winner is announced to obtain funding to cover the shortfall with the support of the relevant liaison person in the SAKK CC.

Should funding not have been secured at the end of the 12-month period, the prize money will go to the best proposal still in need of funding. If there are no more proposals in the running, the prize money will be forfeited and SAKK will use it to finance ordinary clinical cancer research.

4.3 Non-Nominated Proposals

The SAKK CC will reach out to investigators of proposals not selected for nomination to initiate discussions on the subsequent steps in the process. SAKK will, if possible, endeavor to implement all proposals that received a positive assessment.

5. Consent

Participants consent to the conditions set out here. They also consent to their personal data being processed and shared by the SAKK to the extent necessary to conduct the project. They are aware that personal data (particularly names, qualifications, titles, and photos) of the researchers submitting the first-, second-, and third-place proposals will be announced at the award ceremony at SAKK's

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Semi-Annual Meeting and will be published by SAKK on the Internet, social media, and other channels. They consent to such announcements and publication.

6. Legal Recourse

The researchers submitting the first-, second-, and third-placed proposals will be notified in person by mid-June 2024. An award ceremony will be held at SAKK's Semi-Annual Meeting on 26 June 2024. No correspondence will be entered into concerning the assessment procedure. The jury's decision is final and may not be contested by any party. The jury will hold its deliberations and make its evaluations in private.