Research Groups

Project Groups

Breast Cancer

President
PD Dr. med. Marcus Vetter
Cantonal Hospital Baselland, Liestal
Vice president
Prof. Dr. med. Peter Dubsky
Hirslanden Klinik St. Anna, Cham

Review 2024
The SAKK Breast Cancer Research Group made significant progress in 2024 with ongoing and newly initiated trials, key scientific presentations, and impactful collaborations. This annual report summarizes trial activities, patient enrollment, key findings, and forward-looking projects. There is still a high unmet need for new trials that can help to increase accrual and to define follow-up projects. According to our research strategy, there is a lack of trials in the field of certain subgroups, e.g. elderly or very young breast cancer patients.

Key achievements
- Total enrolled patients (2024): 269
- Cumulative patients (2021–2024): 799
- Active trials: 6
- New protocols under Development: 5
- Scientific presentations & abstracts accepted: 6

Collaborations
- SOLTI and Unicancer: Strong collaborations with good outlook.
- BIG/IBCSG: Participation in studies like TARSILIA and OPTIMA-Young. Ongoing discussions for funding for the IBCSG ILC chemo trial.

Conclusion and goals for the coming period
Several promising projects are currently in the pipeline and are anticipated to launch in 2025. However, it is critical that we accelerate progress not only by expediting ongoing projects but also by identifying and prioritizing the most impactful projects in the right strategic areas. To achieve this, a sharper focus on efficiency, resource allocation, and strategic decision-making will be essential.

Equally important is the design and planning of future clinical trials, particularly in alignment with follow-up projects. We must ensure a seamless transfer of knowledge from translational research into clinical applications, bridging the gap between laboratory discoveries and patient care advancements. This requires a more structured approach to knowledge sharing, documentation, and collaboration across teams.
Our core team will be strengthened by the participation of basic researchers, who will actively contribute in 2025. Their expertise will be invaluable in enhancing the scientific depth and innovation of our initiatives.

Additionally, we need to accelerate our negotiations with industry partners to collaboratively design and implement clinical trials more effectively. Strengthening these partnerships will not only facilitate faster trial initiation but also ensure alignment with industry standards, resources, and expertise. Streamlining these collaborations will be a crucial factor in our success moving forward.

Developmental Therapeutics

President
Prof. Dr. med. Anastasios Stathis
Oncology Institute of Southern Switzerland (IOSI)
Vice presidents
Dr. med. Dr. rer. nat. Christian Britschgi
University Hospital Zurich
Dr. med. Martina Imbimbo
Oncology Institute of Southern Switzerland (IOSI)
Prof. Dr. med. Dr. phil. nat. Markus Jörger
Cantonal Hospital St.Gallen

The SAKK Developmental Therapeutics project group leads pioneering work in innovative early phase trials, fostering collaboration on groundbreaking cancer treatments.

Overview
The SAKK Project Group Developmental Therapeutics (PG DT), established in November 2019, was set up by merging the former project and working groups New Cancer Therapies, Immunotherapy, and Molecular Oncology. This reorganization has optimized expertise, enabling robust trials in immunotherapy, non-immunotherapy, and translational research programs.

PG DT has conducted cutting-edge trials involving chemotherapy, targeted therapies, and immunotherapy. The group has also explored combinations with surgery, radiotherapy, and medical devices. Supported by SAKK's eight phase I sites, PG DT collaborates with the pharmaceutical industry, offering Swiss patients early access to innovative treatments.

In 2024, PG DT ran three early clinical trials, enrolling 19 patients, and contributed to four publications based on SAKK 65/16, SAKK 80/19_AlpineTIR, and SAKK 41/16 trials. Two abstracts were presented at major international conferences, based on SAKK 66/22 and SAKK 17/18. For details on publications, please see page 21).

Key active clinical trials in 2024
SAKK 66/22 (NCT06358573): Led by U. Zürrer and M. Jörger, this phase II trial evaluates INT230-6 with pembrolizumab and chemotherapy in early triple-negative breast cancer (TNBC). Swiss sites are enrolling patients, with French sites expected to be activated in 2025.
SAKK 66/17 (NCT03993678): Led by M. Jörger, this trial combines IP-001 with thermal ablation in advanced solid tumors. In 2024, the melanoma cohort continued to recruit, and the sarcoma cohort closed successfully.
SAKK 69/22 (NCT05688280): This international trial, in collaboration with Immunophotonics, tests IP-001 with thermal ablation in colorectal cancer, NSCLC, and sarcoma. Recruitment closed in 2024 after completing patient accrual.

Future goals

PG DT aims to strengthen collaborations with industry and research laboratories in Switzerland and internationally, maintaining close ties with other SAKK groups. In 2024, the group partnered with Nurix Therapeutics for the NX-5948 international trial, a Bruton's Tyrosine Kinase degrader for relapsed/refractory B-cell malignancies, set to begin enrollment in Q1 2025 and led by A. Stathis.

Looking ahead

PG DT is dedicated to advancing innovative cancer treatments through strategic partnerships and impactful research collaborations, ensuring patients benefit from early access to groundbreaking therapies.

Gastrointestinal Cancer

President

PD Dr. med. Alexander Siebenhüner

Clinic for Hematology & Oncology Hirslanden Zurich

Vice president

PD Dr. med. Sara De Dosso

Oncology Institute of Southern Switzerland (IOSI)

The year 2024 was a restart for study activity for the PGGI, as further projects were approved in addition to the DANTE phase III trial and have now been taken into the active phases. The core group also engaged in intensive discussions on new study projects and individual discussions on future study projects and ideas were also held with industry partners at ASCO and ESMO 2024.

Nevertheless, in addition to the activation and the good recruitment phase within the DANTE study, an ambitious goal is to open further clinical trials within SAKK soon. One of the most difficult hurdles, especially for academic studies, is securing funding. To support such concepts of new ideas at an early stage, the strategy for this is discussed in the regular core teams. In addition, a scientific retreat is planned for early 2025 within the In-Between Meeting 1 in Bern in March 2025.

Three protocols with the SAKK 41/23 Partracer, circulate III and the translational program for SAKK 41/46 are currently in final development for the planned opening in 2025.

In addition, new proposals are currently being discussed within a collaboration with the ENGIC Group (ELUCID on MSI-h CRC and immunotherapy), as well as the NEOXY study and an interventional study in metastatic CRC and maintenance therapy in pancreatic cancer with MTAP deletion.

For the publications and abstracts in 2024, please refer to the separate report. The SAKK 41/13 study (Aspirin Trial), which was also presented by Prof. Ulrich Güller at ESMO 2025, deserves special mention and is a source of great pride.

This imaginative and committed PGGI working group – supported by the core team and external advisor Prof. Dr. med. Florian Lordick – can look to 2025 and beyond with confidence.

Gynecological Cancer

President

Prof. Dr. med. Intidhar Labidi-Galy

Geneva University Hospitals HUG

Vice presidents

Dr. med. Ilaria Colombo

Oncology Institute of Southern Switzerland IOSI

Dr. med. Ursula Hasler-Strub

Cantonal Hospital Graubünden

In 2024, the newly created Project Group (PG) Gynecological Cancer achieved several successes.

Ongoing trials

The SAKK/SCORED_OvCaR – the Swiss Registry of Ovarian Cancer– that ensured funding for 500 patients, started enrollment in Q4 2023. It is the first Swiss registry on gynecological malignancies and has the important objective of collecting real world data to further sustain clinical research in ovarian cancer within our group. By Q4 2024, 14 sites have been activated and it has recruited more than 250 patients, reaching half of the planned enrollment in one year. Activation of additional Swiss sites is ongoing.

The MK-2870-005/ENGOT-en23/MITO trial, a pivotal randomized phase III trial comparing MK-2870, an antibody-drug conjugate anti-Trop2 to physician therapy choice in relapsing endometrial cancer has opened in Q2 2024. So far, four sites have been activated in Switzerland and ten patients already randomized, achieving 40% of the planned enrollment within six months. This exceptional achievement reflects the commitment of the Gynecological Cancer PG members that refer patients to open sites.

New trials in preparation

Several new trial proposals presented at ENGOT meetings have been discussed and might be initiated in the future. These trial proposals cover a range of innovative and potentially practice-changing therapeutic approaches in gynecological cancers (surgery de-escalation, ADC, target therapies etc.). The PG is also working on the development of new SAKK trial proposals in the field of surgical intervention in endometrial cancer, ctDNA monitored treatment in locally advanced endometrial cancer, neoadjuvant strategy for locally advanced cervical cancer and new approaches of immunotherapy in ovarian cancer. Funding applications have been submitted to different foundations. Together, the diversity of initiated trials and proposals currently under development reflect the dynamism and commitment of the Project Group Gynecological Cancer.

Leukemia

President
Prof. Dr. med. Alexandre Theocharides
University Hospital Zurich
Vice president
Dr. med. Corinne Widmer
University Hospital Basel

As 2023, 2024 was another demanding year for the Project Group Leukemia. Only one trial was open for recruitment, whereas the next generation was not yet ready for activation.

Presidency
Prof. Dr. med. Thomas Pabst (Inselspital Bern) resigned as president after six years of excellent work for the group.
Prof. Dr. med. Alexandre Theocharides (University Hospital Zurich) was elected as the new president of the PG Leukemia at the semi-annual meeting in September. His candidacy was approved by the SAKK Board in November.

Progress in trials
Overall, the trial activity in the group was very limited since only the HOVON 150 trial was open for recruitment in 2024. The patient recruitment ended in September 2024 with 63 of the planned 80 patients included in Switzerland (29 for the IDH1 and 34 for the IDH2 cohort). In the HOVON 156 cohort, the primary end point was changed from EFS to OS. The final analysis of the CLL-17 is expected in 2027.

Outlook
We expect multiple new trials to open in 2025. In particular, the new generation of HOVON studies, the HOVON 173 (EVOLVE-1), the HOVON 177 (EVOLVE-2), and the HOVON 501 trials will launch in 2025. These are all phase III trials, which aim at investigating targeted therapies in combination with standard AML treatment. The HOVON 173/177 trials are designed for AML patients ineligible for intensive chemotherapy. They will combine the IDH1 inhbitor ivosidenib in IDH1 mutated AML (EVOLVE-1) and the menin inhibitor revumenib in NPM1/KMT2A mutated AML with Azacitidin and Venetoclax (EVOLVE-2) in the experimental arm. Both are scheduled to open in Q2/2025. Fortunately, the toxicity issues faced in the establishment of the HOVON 501 study could be resolved. The HOVON 501 trial will combine Venetoclax with standard chemotherapy (3+7) in patients fit for intensive chemotherapy. This trial is expected to launch Q3/Q4 2025. There are ongoing discussions about an EORTC trial in AML combining the BCL-2 inhibitor sonrotoclax in with ASTX727 in fit patients 60 years or older.

The GRAALL-2024 will evaluate the role of new immunotherapeutic agents in frontline therapy of adult patients with acute lymphoblastic leukemia (ALL) and the role of allogeneic hematopoietic stem cell transplantation (HSCT) in the Philadelphia-positive subgroup. The trial is scheduled to open in Q1/Q2 2025.

The CLL-18 trial will investigate MRD-guided venetoclax/pirtobrutinib vs. fixed duration venetoclax/pirtobrutinb vs. fixed-duration venetoclax/obinutuzumab in patients with previously untreated CLL/SLL. The recruitment is planned to start in Q3/Q4 2025.

In summary, after two difficult years, the group is optimistic that the trial landscape will significantly evolve, and patients will finally benefit from trial opportunities in 2025.

At the organizational level, a new group vice chair will be elected in 2025 and a detailed timetable has been communicated to all group members.

Lung Cancer

President
Prof. Dr. med. Alessandra Curioni-Fontecedro Cantonal
Hospital Fribourg HFR
Vice presidents
Dr. med. Laetitia Mauti
Cantonal Hospital Winterthur
Prof. Dr. med. Alfredo Addeo
Geneva University Hospitals (HUG)

Read the report on pages 14–15 of the Annual Portrait 2024.

Lymphoma

President
Prof. Dr. med. Francesco Bertoni
Institute of Oncology Research, Università della Svizzera italiana (USI)
Vice president
Prof. Dr. med. Thorsten Zenz
University Hospital Zurich

Highlights
Our group included 54 patients in 2024; 33 in interventional trials (SAKK 38/19 and SAKK 38/23) and 21 in the European Mantle Cell Lymphoma Network (EMCL) registry.

The SAKK 38/19 for diffuse large B-cell lymphoma (DLBCL) patients has been designed by PG investigators with Anastasios Stathis as the principal investigator (PI). It is an exploratory multicohort phase II trial exploring the addition of the second-generation BTK inhibitor acalabrutinib to standard regimen R-CHOP only to a subset of DLBCL patients bearing specific genetic lesions, as defined by liquid biopsy on circulating tumor DNA (ctDNA), and the integration of ctDNA levels

with PET imaging to decrease or intensify treatment. The trial, also open in a few Italian centers, completed its enrollment in June 2024. It was very successful in implementing all the procedures which are now in place and available for future trials. A first abstract will be submitted to the 2025 ICML, while follow-up is needed to look at the study end points. Discussions are ongoing on the design of possible future trials in this patients population.

In 2024, the PG Lymphoma opened the SAKK 28/23 LIBERTY, investigating whether the detection of circulating tumor DNA (ctDNA) in cerebrospinal fluid can be used to determine more easily and precisely than before whether CNS involvement is present in B-cell lymphoma patients with a high risk of such CNS complication or whether the risk of this is increased. The trial, with Noémie Lang as PI, won the 2023 first SAKK Network Trial Award with prize money of CHF 1 million.

The international phase III academic trial MorningLyte compares the combination of mosunetuzumab, a bispecific antibody that targets CD20 and CD3 and redirects T cells to attack and eliminate malignant B cells, with the immunomodulator lenalidomide versus the standard chemoimmunotherapy in previously untreated FL patients. The study was approved by the PG Lymphoma in 2023, and, after some delays, enrollment opened in June 2024, starting in France and Belgium. The trial is about to finally open for the PG Lymphoma centers, with Carmen Julia De Ramón Ortiz, as Swiss PI.
In 2024, the PG Lymphoma also opened the IELSG48 trial. This is a phase III randomized study comparing rituximab plus zanubrutinib to rituximab monotherapy in previously untreated, symptomatic splenic marginal zone lymphoma.

New trials in the pipeline

A phase I study exploring a BTK degrader, approved by the PG Lymphoma in 2023, is about to start enrolling. Administrative discussions are ongoing between SAKK and the company to open a phase I study, exploring the combination of two bispecific antibodies, also approved in 2023.

The group has been working with other cooperative groups to open new trials for patients affected by mantle cell lymphoma, Hodgkin lymphoma, multiple myeloma (MM), and Burkitt lymphoma.

Once again, the group achieved a high scientific output, with various publications in the Journal of Clinical Oncology, Lancet (twice), Leukemia, and Journal of Nuclear Medicine, as well as oral contributions and posters at the ASH and EHA.

Urogenital Tumors

President
Dr. Ursula Vogl
Oncology Institute of Southern Switzerland (IOSI)
Vice president until end of 2024
Dr. med. Alexandros Papachristofilou
University Hospital Basel

New group president – new clinical project manager – a challenging restart of the Urogenital Group – but with a positive dynamic throughout the year

In 2023, unfortunately, due to the lack of funding, some important trial concepts, already having passed the SAKK Scientific Committee, could not be realized. This led to a certain stagnation and frustration of the group dynamic when PD Dr Ursula Vogl took over the group as president in the beginning of 2024. Martina Schneider, our clinical project manager for several years and with an established role, also stepped down from her position and was replaced by Zuzanna Maniecka Moser, who quickly took over her tasks successfully. Though with a strong base from the continuing vice president and a group of regularly participating and contributing PG UG members, new positivity was felt in the group dynamic. For example, we've organized at the semi-annual meeting in May 2024 the first SAKK Consensus Meeting on systemic treatment of urothelial carcinoma with a strong participation and dedication from the current group members, allowing also to reacquire former and to welcome new group members also from urology. Moreover, very positive is the enthusiasm of the SAKK young academy participants represented by radiotherapy, urology and oncology. All three participants had the opportunity to present themselves and their research with their mentors at the open part of the semi-annual meeting and at closure of their academy in November 2024. One of the young SAKK academy participants presented already two trial proposals by the end of 2024.

Regular core group meetings have been essential to set goals, allocate resources and correctly prioritize.

Two group vice presidents newly voted at the end of 2024 – a novelty in the PG UG

Dr. Papachristofilou finished his term as group vice president by the end of 2024 and at the SAKK semi-annual meeting in November 2024, two vice presidents were invited to candidate. PD Dr Mohammed Shelan (radiation oncologist) and Prof. Dr. Christian Fankhauser (surgical urologist) were elected and joined the team as vice presidents, allowing to have all main specialists for urogenital tumors represented as group leaders.

Project Group Trials accrual and status of open trials by the end of 2024

Our group recruited 63 patients into four open studies during 2024 (comparatively stable to the year before). A great effort was seen to enroll in the final months of SAKK 96/12, an investigation of de-escalation of the bone-modifying agent denosumab in metastatic prostate and breast cancer. The temporarily paused SAKK 06/19, a trial investigating a combination of chemotherapy, immunotherapy and intravesical therapy in muscle-invasive bladder cancer trial, could recruit extremely well after reopening in 2024. SAKK 01/18, a clinical trial investigating de-escalated chemotherapy and radiotherapy in stage IIA/B seminoma—and the largest study to date in this indication with the potential to establish a new standard of care—successfully completed accrual by the end of 2024 following the addition of an expansion cohort. This marks another significant achievement.

Group meetings discussed several new trial proposals following consultations in the core team that met regularly.

The already established SAKK Translational Urogenital Cancer Network Meeting and the SAKK GU Cancer Forum will continue on a regular basis as an essential moment of the SAKK PG UG.

Opening of a new randomized international phase II trial SAKK 08/23 in metastatic castration-resistant prostate cancer

By the end of 2024 the phase II randomized trial SAKK 08/23 (PIs Prof. Richard Cathomas, PD Dr. Ursula Vogl) investigating the role of maintaining the ARPI added to ADT in metastatic hormone-sensitive prostate cancer in long responders together with the first-line mCRPC standard of care by investigator's choice, was opened. The trial opened in a large number of Swiss sites and will open soon at the collaboration partner sites from SOGUG in Spain.

Reaching out for new collaborations with international academic groups

A first informative virtual call was held in 2024 with the Irish academic group (Cancer Trials Ireland – Lead Prof. Ray McDermott), a group renowned for their collaboration with STAMPEDE and the Australian research group ANZUP. We shared out trial portfolio and research interests and will keep in contact. Participation as a guest in one of the group meetings in 2025 is planned, fostering further collaboration and exchange of ideas.

Outlook 2025

Continuing collaboration with STAMPEDE

Already in the past, the PG UG historically collaborated and contributed to several arms of the STAMPEDE trial, a multi-arm, multi-step platform randomizing prostate cancer patients to various treatments in different disease settings. The STAMPEDE 2.0 oligometastatic arm found full dedication from the group and grant funding was acquired by two radiotherapists from the group, making the trial opening in 2025 possible. Another arm of STAMPEDE 2.0 including Lutetium-PSMA requiring a strong collaboration with the nuclear medicine physicians is under discussion for feasibility in Switzerland.

Current trial proposals and trials in development

Trial proposals are in development also in the non-prostate field, one of them approaching an area of high research interest – improving bladder-sparing concepts in muscle-invasive bladder cancer.

A prospective registry in testicular cancer is also in planning, following the great success of SAKK 01/18.

An unmet need remains trial proposals for renal cell carcinoma (RCC). Unfortunately, an approach to collaborate with GETUG in a phase III trial, currently already recruiting internationally in first-line metastatic clear cell RCC failed to open due to the lack of possibility to modify the collaboration partners (in that concrete case SAKK) in the European Union Grant HORIZON (amendment only once yearly possible in the trial protocol).

A strong focus remains on prostate cancer trials, numerous are under development and are searching for funding.

Some examples: The phase II trial ISOTONIC (PI Prof. Dr. med. C. Fankhauser) has received the SAKK network trial award and therefore has a good chance with additional funding in discussion with the investigational drug sponsor to be realized for opening in 2025. A trial proposal for a de-escalation in mHSPC lead by the EORTC, represented by two group members that are international PIs (Prof. Silke Gillessen and young PI Dr. Fabio Turco), is under way to acquire funding to open soon in Switzerland.

In conclusion, the SAKK PG UG looks positively into the upcoming year 2025 with several trails in development, with a good chance to open already by the end of 2025. We plan to invite also a nuclear medicine physician to our Core team meetings since more trials with radiopharmaceuticals are coming up, requiring strong collaboration.

Working Groups

Cellular Therapies

President
Prof. Dr. med. Dr. phil. George Coukos
Lausanne University Hospital (CHUV)
Vice presidents
PD Dr. med. Dr. Francesco Ceppi
Lausanne University Hospital (CHUV)
PD Dr. med. Michael Daskalakis
Inselspital Bern (University Hospital of Bern)
Prof. Dr. med. Heinz Läubli
University Hospital Basel
Prof. Dr. med. Dominik Schneidawind
University Hospital Zurich

Intensifying cooperation
During 2024, SAKK's Working Group Cellular Therapies (WG CT) continued its efforts to advance cellular therapy initiatives through collaborative projects and clinical trials. A key focus was on the development of a proposal for a randomized trial titled "A randomized trial assessing the impact of prophylactic anakinra to reduce ICANS after CAR T cell therapy for lymphoma." This proposal, led by PI Arber and co-PI Schneidawind, was submitted for the SAKK award but was not funded. While an SNF IICT application was considered, the proposal's feasibility challenges and its limited focus on CAR T cells from a single company (Kite Gilead) led to a decision not to submit.

Efforts are now underway to engage Kite Gilead to explore their interest in the project. Additionally, discussions with SOBI have been initiated to evaluate potential co-funding opportunities and secure anakinra as a complimentary resource. These steps underline WG CT's proactive approach to fostering industry partnerships and advancing access to innovative cellular therapies.

Another significant collaboration involved Benjamin Kasenda (USB), who contributed to the design of the bendamustine trial for CAR T lymphodepletion. The trial was also proposed to the Project Group Lymphoma, further emphasizing the importance of cross-disciplinary cooperation.

Advancing clinical trials
In 2024, WG CT focused on several local trials aimed at exploring innovative therapies:
- **BaseTIL-03M:** TIL therapy combined with ANV419 for patients with advanced melanoma who failed standard therapy (PI: Heinz Läubli). Seven out of ten patients have been included in this trial (NCT05869539).
- **BaseTIL-02:** TIL therapy for patients with NSCLC after first-line therapy (PI: David König, NCT06455917).
- **CHUV-DO-0026_NYESO1-2023:** A phase I study evaluating safety and feasibility of redirected autologous T cells expressing a high affinity TCR specific for NY-ESO-1 (LauT-1) in patients with advanced melanoma and sarcoma (PI: Bernhard Gentner) (NCT not yet available).

Upcoming and restarting trials:
- **CD19/20 CAR Ts:** A trial for patients with B cell lymphoma is about to start after the completion of three validation runs (PI: Andreas Holbro).
- **NK Trial:** A trial for AML patients post-haplo transplant is about to restart (PI: Köbi Passweg, NCT03300492).

Ongoing studies:
- **Virus-Specific T Cells:** A study investigating virus-specific T cells, including for EBV-driven cancers (PI: Nina Khanna, NCT05688241).

These trials represent WG CT's ongoing dedication to advancing cellular therapy options for Swiss patients through innovative research and collaboration.

Challenges:
The coordination of efforts between CT WG and other SAKK groups for the common advancement of studies requires optimization and some mechanism that reinforce central or dual approval.

These trials represent WG CT's ongoing dedication to advancing cellular therapy options for Swiss patients through innovative research and collaboration.

Challenges:
The coordination of efforts between CT WG and other SAKK groups for the common advancement of studies requires optimization and some mechanism that reinforce central or dual approval.

CNS Tumors

President
Prof. Dr. med. Philippe Schucht
Inselspital Bern (University Hospital of Bern)
Vice president
PD Dr. med. Dr. phil. Emilie Le Rhun
University Hospital Zurich

The Working Group Central Nervous System Tumors (CNS Tumors) currently has 68 members. It maintains synergistic relations with the Swiss Neuro-Oncology Society.

In 2024, working group members continue to conduct several clinical trials

Trials involving primary brain tumors
The multicenter RESDEX trial is investigating the impact of perioperative steroids on patient care, complications and clinical outcome. The trial currently has three Swiss sites (Bern, Basel

and St. Gallen) and has recruited 32 of the 50 target patients. The trial is scheduled to conclude in 2026

The multicenter, randomized, controlled RESURGE trial is investigating the overall survival impact of surgical treatment of recurrent glioblastoma. It is being conducted at 25 Swiss and European sites. At present, 43 out of 120 patients have been recruited for the randomized part of the trial, with an additional 35 patients in the observation cohort. 8 French centers will join the study to increase recruitment efforts.

GLIOSTAR: The GLIOSTAR trial aims to investigate the safety and efficacy of L19TNF plus lomustine in patients with glioblastoma in the first stage of progression. The primary end point is overall survival. The randomized part of phase II was activated. Patients are randomized at a ratio of 1:1 and receive either lomustine and L19TNF or lomustine on its own. 106 out of 158 patients have been enrolled.

GLUGLIO: The primary goal of the randomized 1:1 trial of glutamate signaling inhibitors in glioblastoma is to explore the efficacy of a combination of gabapentin, sulfasalazine, memantine and standard chemoradiotherapy versus standard chemoradiotherapy alone in patients with newly diagnosed glioblastoma. The primary end point is PFS-6. The trial is aiming to enroll 120 patients, recruitment is ongoing.

LEGATO: Lomustine with and without reirradiation for first progression of glioblastoma: a randomized phase III trial. The primary goal is to demonstrate whether reirradiation combined with lomustine is beneficial to survival when compared with lomustine alone in patients with initial progression of their glioblastoma. This EORTC trial is funded by an EU subsidy that does not extend to Switzerland's participation. We are currently trying to find a way of enabling Switzerland to take part in this important initiative. Enrolment planned Q12025 (Zurich and Bellinzona).

GLIOSUN: Safety and efficacy of L19TNF plus temozolomide chemoradiotherapy in patients with newly diagnosed glioblastoma. The aim of the study is to evaluate the safety, tolerability, efficacy and optimal dose of the new drug L19TNF with potential anticancer activity plus standard radiotherapy and temozolomide in patients with newly diagnosed glioblastoma. phase I and phase II target number of patients phase II: 32, enrolment is ongoing.

AGILE: A Trial to Evaluate Multiple Regimens in Newly Diagnosed and Recurrent Glioblastoma
Glioblastoma (GBM) adaptive, global, innovative learning environment (GBM AGILE) is an international, seamless phase II/III response adaptive randomization platform trial designed to evaluate multiple therapies in newly diagnosed (ND) and recurrent GBM. Current Status: enrolment ongoing.

ACTION: ONC201 in H3 K27M-mutant Diffuse Glioma Following Radiotherapy (the ACTION Study)
Randomized, double-blind, placebo-controlled, parallel-group, international, phase III study in patients with newly diagnosed H3 K27M-mutant diffuse glioma to assess whether treatment with ONC201 following frontline radiotherapy will extend overall survival and progression-free survival in this population.

The primary end point is overall survival. Target number of patients: 450. Current status: enrolment ongoing (Zurich and Lausanne).

Trials involving metastatic CNS cancer
IT-IO: Intrathecal administration of anti-PD1/anti-CTLA-4 in combination with a systemic combination of anti-PD1/anti-CTLA-4 in patients with NSCLC or melanoma and recently diagnosed leptomeningeal metastases: a multicenter phase I trial. This Swiss trial sets out to determine the recommended phase II dose of intrathecal nivolumab and ipilimumab. It aims to enroll 15–26 patients. The expansion phase is open.

STRIKE: Immunotherapy or targeted therapy with or without stereotactic radiosurgery for patients with brain metastases from melanoma or non-small cell lung cancer is a prospective, multicenter, randomized (1:1) open-label phase III superiority trial. The aim of this international trial is to assess the additional benefits of SRS in advance of systemic standard therapy in newly diagnosed brain metastases. The trial is aiming to enroll 190 patients. As yet 12 patients have been included. Site activation is still ongoing.

Partially funded by the Belgian Foundation Against Cancer, EVIDENCE has as primary goal to collect data to demonstrate superiority in terms of overall survival of an arm managed by pharmacoscopy compared with an arm that is not managed by pharmacoscopy (2). The trial is aiming to enroll 102 patients. The protocol is in development.

Varia
Swiss Brain Tumor Foundation Cohort Study aims to analyze specific populations of interest such as glioblastoma long survivors (> 5 years), IDH mutant glioma, Vortioxetin-treated patients. Data entries were initiated.

Head and Neck Cancer

President
Dr.ssa. med. Vittoria Espeli
Oncology Institute of Southern Switzerland (IOSI)
Vice president
Prof. Dr. med. Panagiotis Balermpas
University of Zurich and University Hospital Zurich

Since 2022, our presidency of the SAKK Head and Neck Working Group was able to maintain the interest of all members, in particular establishing an active collaboration within the different specialties.

The core team met regularly, and, with the support of our international advisor Prof. Jan Vermorken, a disease area strategy was defined. In particular, we defined our research focus with the aim to coordinate our work for trial proposals answering the raised questions based on unmet needs.

Several study proposals were discussed, presented and voted during the semi-annual meetings.

Study partially supported by SAKK

The PROLoNg trial is an international intergroup phase III trial in cooperation with EORTC evaluating the role of adding local stereotactic ablative radiotherapy to standard pembrolizumab for patients with oligometastatic head and neck cancer. The European ethical committee approved the study and the contract is completed between EORTC and SAKK. SAKK will soon begin regulatory submissions in Switzerland and we will open the trial end of Q1 or Q2 2025.

Grant applications

The network is very active and we submitted three new study proposals to SAKK, which did not agree to support our applications financially. This is why we submitted our study proposals to obtain grants outside SAKK but in close cooperation with the SAKK scientific officers.

1) Curative setting

Refining treatment after subtotal/total glossectomy: hypoglossal nerve centered resection and neurotized profunda artery perforator (PAP) flap.

This is a surgical trial evaluating a new technique for patients with tongue cancer treated with curative intent with the goal of improving function and quality of life.

Several SAKK sites and MD Anderson agreed to participate. An SNF grant application is ongoing.

2) Palliative setting

Local therapy for metastatic SCCHN

This is a prospective randomized phase II trial evaluating the role of adding local treatment (radiotherapy or surgery) to standard systemic treatment for patients with both local and metastatic diseases. Retrospective data indicate a clearly improved outcome for this difficult-to-treat cohort. An SNF application will be prepared soon.

Treatment sequencing for locoregionally recurrent SCCHN

This prospective-randomized trial tries to answer which systemic treatment sequence is better for patients with locoregionally recurrent disease. This cohort is currently treated identically to metastasized patients, however, was always underepresented in landmark trials and the results with the current strategies are disappointing. The study will compare, in an innovative approach, different sequencing strategies of chemo- and anti-EGFR treatment followed by immunotherapy or vice versa.

Discussions with several pharmaceutical companies for financial support have been conducted.

Collaboration within SAKK groups

Effect of early palliative care on quality of life for patients with relapsed/metastatic head and neck cancer

This is a new study proposal in collaboration with the Working Group Supportive, Palliative and Geriatric Oncology. The pre-feasibility survey and the positive vote of both groups have been obtained, the statistical analysis conducted, and the protocol is under development.

Rare diseases and Swiss recommendations

The group gives importance not only to clinical trials but also to open the room for new collaborations.

SAKK registry and digital platform for rare diseases

Rare diseases represent part of the daily clinical activity of head and neck oncology.

There are different examples of registries or digital platforms applicable for rare head and neck tumors.

We want to evaluate a registry with the aims to develop a new way to analyze and interpret nation-wide medical data.

Do we need a Swiss consensus in head and neck oncology?

The Working Group Head and Neck Cancer published some years ago that there is no consensus for several topics in head and neck oncology within the Swiss centers.

As a research society, we want to collaborate more with other societies involved in head and neck cancers treatment to define expert opinions for topics with insufficient evidence. For this purpose, we are in contact with the Swiss Head and Neck Society and discussions are ongoing.

Outlook

We are working to further strengthen head and oncology within SAKK. Lack of funding for ideas is a common problem, but we are looking forward for further support from the SAKK headquarters, also in establishing relationships with pharmaceutical companies and charity organizations.

In the upcoming year, we aim to open at least two of the above trials, establish a registry for at least one rare indication and lunch a cooperation with the Swiss Head & Neck Society.

Imaging in Diagnostic and Therapy Monitoring

President

PD Dr. med. Andreas Hötker

University Hospital Zurich

Vice president

Prof. Dr. med. Lukas Ebner

Inselspital Bern (University Hospital of Bern)

Publication of a consensus paper
The group is dedicated to emphasizing the crucial role of imaging in cancer diagnosis and therapy monitoring. In 2024, the group published a consensus paper on the advantages and challenges of certain imaging modalities in the staging of lung cancer. This effort is aimed to improve the consistency, reliability and comparability of trials in this field.

Standardizing imaging protocols
The Working Group Imaging in Diagnostic and Therapy Monitoring is a cross-trial working group within SAKK. Specialists in radiology and nuclear medicine from various Swiss medical centers contribute their expertise and help assess imaging-based end points for all SAKK trials involving imaging. The publication of a white paper on imaging of lung cancer reflects the group's collaborative approach to provide nationwide standardized guidelines and evaluations for imaging that will improve the compatibility and interpretability of the data.

It is our opinion that a general imaging guideline for scientific studies will simplify the implementation of imaging in trial protocols and provide information on the correct use of imaging in a specific research issue.

The Working Group Imaging in Diagnostic and Therapy Monitoring will of course continue to assist all members in determining imaging-related end points as needed.

Thanks
We would like to thank everyone, including radiologists, researchers and institutions, for their dedication and expertise during the drafting of the white paper. The contributions from specialists throughout Switzerland have shown that there is a lot of interest in standardizing investigation methods. Using the imaging guideline for lung cancer as a starting point, future projects will progressively address other organ systems too.

Melanoma

President
Dr. med. Joanna Mangana
University Hospital Zurich
Vice president
Dr. med. Ioannis Metaxas
Spital Thurgau AG

Due to the major achievements and several approved therapeutic regimens during the last years in melanoma field, initiation of national phase I–II trials becomes challenging.

The ENiGMA: Open label, non-randomized, phase IB study to characterize safety, tolerability and recommended dose of tinostamustine (EDOS101), a first-in-class alkylating histone deacetylase inhibitor (HDACi) fusion molecule, in combination with Nivolumab in patients with refractory, locally ad-vanced or metastatic melanoma finished accrual last year and was presented in ESMO 2023. In total, 17 patients were included with the majority of those being pretreated; the combination showed a DCR of 69% (46% SD and 23% PR) and a mPFS of 8.3 weeks. Publication is pending.

SAKK 66/17: Thermal laser ablation and intratumoral injection of IP-001 in patients with advanced solid tumors recruits very well in soft tissue tumors, the recruitment in melanoma patients is however challenging. The study is still open, the majority of already included patients had poor prognostic factors or also were non-cutaneous melanoma (uveal). There are currently three sites accruing patients: Bern, Chur and St. Gallen.

Analysis of CTLA-4 Single Nucleotide Polymorphisms (SNPs) as possible surrogate markers for the outcome of ipilimumab-containing regimes in melanoma: After successful publication of the research project, BMS agreed on supporting a validation analysis from the phase III CM-067 clinical trial.

MelChrono on the optimal time point of immunotherapy has been resubmitted for SNF funding. Several other proposals on the optimal cycles of combination immunotherapy (2 versus 4) and also a shorter adjuvant anti-PD1 treatment. The proposals will be rediscussed in 2025.

The group was able to include a total of 702 patients in the SCORED registries (SAKK 80/19 Alpine-TIR).

Outlook
Swiss melanoma guidelines have been submitted for publication.

Sarcoma

President
PD Dr. med. Antonia Digklia
Lausanne University Hospital (CHUV)

The Working Group Sarcoma enjoyed brisk trial activity during 2024.

Activities
The TNT-HYPE trial "Feasibility of Total Neoadjuvant Treatment with HYPErthermia in high-risk extremity and trunk soft tissue sarcoma: A multicenter, single-arm phase II trial" under the direction of Dr. med. Emanuel Stutz and PD Dr. med. Attila Kollar (University Hospital of Bern) received the grant of CHF 900.000 from the Swiss National Science Foundation. In this context, the trial secured funding and the trial will be activated on 2025 in several centers in Switzerland.

Ongoing activities
Collaboration in the International Research Environment
Following close cooperation between SAKK and the Swiss Paediatric Oncology Group (SPOG), under SPOG's lead, the Working Group Sarcoma successfully facilitated participation

in the INTER-EWING-1 trial. This is a prospective randomized phase III trial under the direction of Prof. Bernadette Brennan (UK) that will be investigating several important issues relating to optimum treatment of Ewing sarcoma patients, including in particular maintenance drug therapy. Unfortunately, although it was foreseen that the trial would be submitted to ethics committees and Swissmedic in mid-2024, there was a delay with the outstanding contract with the sponsor (Cancer Research UK Clinical Trials Unit). Currently, we estimate that the submission will take place in Q1 of 2025. Prof. Brennan confirmed that Swiss sarcoma sites' participation in this international trial is important and it will be a priority from their side to advance with the contract.

Talidox

The study group and the sarcoma centres (Zurich, Winterthur, Lausanne, Ticino, St. Gallen, Bern and possibly others) are interested in setting up the study with Innomedica in first-line setting for sarcoma patients. The group will continue discussions with the company in the next months.

Visibility

The new president of SAKK WG Sarcoma is part of the Scientific Committee of ESMO Sarcoma and Rare Cancers.

Supportive, Palliative and Geriatric Oncology

President
Prof. Dr. med. David Blum
University Hospital Zurich
Vice president
Dr. med. Vérène Dougoud
Cantonal Hospital Fribourg HFR

The SAKK Working Group Supportive, Palliative and Geriatric Oncology held its meetings to discuss ongoing studies, new proposals, and updates. The expansion to geriatric oncology (V. Dougoud/M. Vetter) has been very fruitful, with a survey concerning the topic in Switzerland.

The discussions covered the progress of various clinical trials, including ethical dilemmas in phase I trials (Annina Seiler), decisional conflict in cancer trials, and quality of life versus length of life assessments in oncology (S. Stoffel). Several studies are still seeking ethics approval or funding. Contacts to other groups of the SAKK have been intensified.

Among the new proposals, the integration of early palliative care for head and neck cancer patients was approved (V. Espeli/D Blum), with further development planned with the Working Group Head and Neck Cancer. Another proposal focused on evaluating geriatric assessments for predicting treatment toxicity in older patients receiving advanced immunotherapies (W. Rösler). Additionally, there was a suggestion to create an app-based registry for geriatric cancer patients to track patient-reported outcomes and treatments (A. Trojan).

The group reviewed updates from the SAKK Scientific Committee and Competence Center, with announcements regarding new staff, project funding, and study approvals. Discussions also included data collection efficiency in ongoing trials, ongoing efforts to standardize palliative care interventions and strategies to enhance patient recruitment.

Amongst focusing on elderly cancer patients, collaborations with other groups and integration of assessments and patient reported outcomes into clinical trial is a goal for next year.

Sections

Network for Outcomes Research

President
PD Dr. med. Cédric Panje
Hirslanden Radiotherapy
Vice president
Vacant

In addition to selected SAKK trials and literature-based modeling, the Network for Outcomes Research focuses heavily on health economic analyses.

Several health economic analyses using literature-based modeling are currently in progress, e.g. the cost efficiency of adjuvant radiotherapy in ductal carcinoma in situ (DCIS).

Study in development

In addition to the health economic aspects, our section is also supporting research into patient reports of results, such as the study "Assessing medical professionals and cancer patients' preferences for quality of life (QoL) and length of life (LoL) in oncology: a study on gastric and esophageal cancer." The study is completely funded by the foundation Krebsforschung Schweiz and will recruit patients in 2025.

Ongoing SAKK trials

The Network for Outcomes Research is currently involved in two ongoing clinical SAKK trials:
In a health economic project work stream of SAKK 96/12 (prevention of symptomatic skeletal events with denosumab administered every four weeks versus every 12 weeks), inpatient and outpatient costs are collected from hospitals using specific resource use forms and utilities are collected within the trial using EQ-5D instrument, as a basis for calculating quality-adjusted life years (QALYs). The recruitment for this trial ended in March 2024. In order to secure funding for the health economic analysis of the collected data, a grant application has been submitted to Swiss Cancer Research in July 2024.

Furthermore, the health economic analysis for SAKK 80/19, the AlpineTIR immunotherapy registry, is planned for 2025.

Network for Cancer Predisposition Testing and Counseling

President
Dr. med. Manuela Rabaglio-Poretti
Inselspital Bern (University Hospital of Bern)
Vice president
Dr. med. Rossella Graffeo
Oncology Institute of Southern Switzerland (IOSI)

Achievements and actions 2024

The core team met three times to discuss updates to the Swiss Guidelines for Genetic Counseling and Testing, the introduction of an updated counseling guide, revisions to the membership rules, current educational activities, upcoming initiatives and current issues in the field of genetics. The following are the goals that were achieved in the year 2024:

- Revision on Art. 12b let. e of HIBO governing risk-reducing surgery (effective in January 2024)
- Revision of the List of Analyses to include the test indication for the therapeutic indication (effective in July 2024).
- Second update of the Swiss Guidelines for Genetic Counseling and Testing for Cancer Predisposition (July 2024)
- Introduction of a new Counseling Guide for Hereditary Prostate Cancer and updated versions of the Counseling Guides for HBOC and Lynch Syndrome (December 2024)
- Adjustments have been made to the membership regulations
- The Swiss counseling and testing guidelines will be reviewed and updated annually, with modifications made directly available on the portal.

Educational activities 2024

Due to the rapid scientific and technological progress in the genetic field, continuous education is essential. The CPTC Network organizes the biannual genetic course in St. Gallen, with sessions taking place alternately in Lausanne and Lugano each year.

Each session typically draws between 40 and 50 participants.

Introductory training courses held in St. Gallen and Lausanne in 2024 were once again successful and well-attended.

In autumn 2024, the inaugural genetic workshop in Ticino, focusing on hereditary prostate and breast cancer syndromes, alongside the 9th genetic workshop in St. Gallen on HBOC (Hereditary Breast and Ovarian Cancer), were both well-received. Additionally, the informational session on familial breast and ovarian cancer in St. Gallen, aimed at patients and their families, also had strong attendance.

The primary objectives of the CPTC Network include: 1) support sharing and improvement of clinical practice of genetic counseling and testing for cancer predispositions, 2) consolidate collaboration between members, who are specialists offering genetic counseling and ordering testing.

To achieve this, the CPTC network continues with monthly collaborative case conferences. These meetings are an opportunity for members to discuss and share guidelines for tailored management of mutation carriers and genetic cancer risk assessment. Average attendance is gradually increasing to around 30 participants.

Three genetic journal clubs held in 2024 covered the following topics:

- **February:** Pregnancy after breast cancer in young women with germline BRCA pathogenic variants: Findings from an international cohort study. Lambertini M, MD, Genoa.
- **May:** Cancer surveillance as a substitute for prophylactic total gastrectomy in hereditary diffuse gastric cancer: A prospective cohort analysis. Schmid S, MD, Lucerne.

– **October:** Updated NCCN guidelines: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic (Version 1.2025 – September 11, 2024); Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric (Version 1.2024 – August 8, 2024). Nerone M, MD, Bellinzona.

In addition, a presentation featuring national and/or international experts in this specialized area is planned for the semi-annual SAKK CPTC meeting. In 2024, the following speakers were featured:

– **Dr. E. Castro, MD,** who spoke in June on "Critical Insights into the Clinical and Therapeutic Impact of Genetic and Genomic Testing for Prostate Cancer Patients, and the Role of the Polygenic Risk Score in Prevention."
– **Dr. M. Yurgelun, MD,** who presented in November on "Pancreatic Cancer Screening."

All educational activities are recognized by various professional associations (e.g., SGMO, SGGG, SGMG).

Future plan

Looking ahead, we intend to maintain our ongoing educational initiatives and expand them by offering webinar sessions with experts in the field, covering relevant and emerging topics.

In January, Dr. De Lorenzi will present on BIA-ALCL in patients with genetic predisposition for breast cancer: our experience and a literature review, and Dr. Churpek will speak on haematological hereditary syndrome in February.

Additionally, with the support of SAKK, we are coordinating the first European Genetic Counseling conference for autumn 2026.

A proposal for a National Registry will be presented at the upcoming Core Team meeting for the Registry Section.

Pathology

President

Dr. med. Anne-Laure Rougement Pidoux
Geneva University Hospitals (HUG)

The Pathology Section offers expertise in tissue selection and validation, morphological characterization, and molecular analysis. By conducting high-quality, accredited molecular analyses and interpreting the results with precision, pathology serves as a key partner in clinical and translational research. Quality assurance is a priority, with a strong focus on pre-analytical and analytical tissue integrity, tumor content evaluation, and adherence to analytical standards.

Given the need for early planning in translational studies, the Pathology Section is committed to providing centralized assessments of both the quality and quantity of pathology samples. Additionally, it is prepared to organize workshops for pathologists with the support of SAKK. Early review of study protocols and projects would also allow for the integration of a translational research component when relevant and help assess the cost-benefit ratio of the proposed pathology analyses.

Radio-Oncology

President

Prof. Dr. med. Nicolaus Andratschke
University Hospital Zurich

Vice president

Prof. Dr. Pelagia Tsoutsou
Geneva University Hospitals (HUG)

Active trials with successful recruitment

Dr. Papachristofilou (University Hospital Basel) is the principal investigator of the recently published seminoma trial SAKK 01/10 and of the follow-up trial SAKK 01/18 which investigates dose-reduced chemotherapy and radiotherapy in stage IIA/B seminoma. This trial was granted an additional enrollment of 35 patients which sucessfully concluded and results are eagerly awaited.

In locally advanced, resectable stage III(N2) non-small cell lung cancer (NSCLC), the SAKK 16/18 trial investigates the immune-modulatory effect of stereotactic radiotherapy directed to the primary only in addition to neoadjuvant chemoimmune therapy. The trial has recruited 77 of planned 85 patients and the University of Tübingen has been accredited as sole German center to support recruitment.

Prof. Andratschke presented as EORTC Co-PI a recent update of the EORTC 1702-HALT trial which formerly was an SAKK collaborative trial. The trial successfully recruited all foreseen patients mid of 2023 and first results after the last follow-up period and the respective numbers of events are expected for Q1 2025.

New upcoming trials and concepts in discussion

Prof. N. Andratschke (University Hospital Zurich) is one the cohort coordinators of the EORTC/ESTRO E2-Radiate ReCare cohort, a prospective observational registry on patients receiving a second course of high-dose irradiation in a previously area. As of now, only three Swiss centers are intended to be opened for trial recruitment by EORTC and this would repre-

sent an opportunity for SAKK to support additional high-recruiting sites with relevant numbers of re-irradiation in participating in this cohort. In addition, a dedicated Swiss participation would enable the increase of the patient cohort by e.g. n=250 pts. and opened specifically to new sites, e.g. brain and H&N.

PD Dr. T. Finazzi also presented a trial concept in collaboration with the Lung Cancer Group.
Optimized radiotherapy for CRT+I/O in unresectable stage III NSCLC. The study had been submitted to the lottery, but was not selected for initial funding. Further funding submissions and industry support were negative, especially as the trial budget evolved as prohibitive. Thus, the decision to stop further development of the trial.

Prof. F. Herera presented the trial "NeCILA – A Phase II non-randomized Study of Neoadjuvant Induction Chemotherapy and Pembrolizumab Followed by Cisplatin Chemoradiation and Pembrolizumab in Locallyadvanced Cervical Cancer." The trial had previously received core group and section support and was again wholeheartedly supported. Extensive discussion on optimal end point for study discussed as well as exploratory end points including MR imaging based response assessment were taking place and considered by the PIs.

Registry

President
PD Petros Tsantoulis, MD, PhD
Geneva University Hospitals (HUG)
Vice president
Ulf Petrausch
Onkozentrum Zurich

SAKK's Section Registries is embedded in an increasingly busy data ecosystem within Switzerland. DigiSanté is the program set up by the FDHA to promote digital transformation in the healthcare sector. Having been mandated by the Federal Council, it is being drawn up by the Federal Office of Public Health (FOPH) and the Federal Statistical Office (FSO) with an implementation planned from 2025 to 2034.

Swiss OncoData Infrastructure (SODI)
As part of the continuous improvement of SAKK interoperable data semantics, new code data set, the Swiss OncoData Infrastructure (SODI) was developed. SODI is SAKK's infrastructure project for standardized registries and is the preferred data standard. SODI is mapped with the SPHN/SPO dataset and is also aligned with the NICER dataset, including approximately 180 variables.

Registration and Eligibility
PIC / Eligibility Criteria
Demographics and Background information
Year of birth, sex, height Smoking habits, atopy autoimmune disorders
Follow-up / Patient status
Survival status, date of death
Oncological diagnoses
ICD-10 Topography / Morphology TNM / Staging / Grading
Comorbidities
ICD-10
Drug therapies
ATC Reason to stop drug Indication
Radiotherapies
Procedure and target body site Indication
Surgeries
CHOP code
Other therapies
Indication
Tumor assessments
Response Method of assessment Progression
Physical Examinations
ECOG Body weight
Laboratory
Tumor marker
Immunohistochemistry / FISH
Genomic testing / NGS
Gene panel test name ctDNA fraction and MSAF MSI and TMB Gene alterations / VAF CNV and rearrangements

For more details please refer to the latest version of the SAKK SODI Core Data Set.

The SPO-NDS project, funded by the SPHN, is a precision oncology initiative that aims to implement and test new assays such as in vitro drug testing and single-cell analyses prospectively through the National Molecular Tumor Board. As announced in 2023, the project was submitted to the Director's Committee and received significant financial support. The SAKK Competence Center (CC) is ready for data transfers and the inclusion of the first patients is expected in early 2025.

Ongoing and candidate registries
Two registries are currently recruiting: LuCa and OvCaR. LuCa is a registry for lung cancer patients with EGFR mutations. OvCaR is a registry of ovarian cancer patients. Patient accrual is

progressing as planned for both. Two new candidate registries were presented in the core team meetings and are currently in search of funding.

Challenges and outlook

Although significant work has been done to reduce the cost of registries and the overhead of data collection, funding is the main limitation for most candidate projects. A recent study of deviations from prospective clinical trials demonstrated that it should be possible, maybe even necessary, to restrict data collection to the variables that are absolutely necessary. Additional measures to streamline data collection, facilitate data collection and reduce cost are being considered and will be a priority in the coming year.

The SAKK CC has demonstrated the capacity to collect data at a national scale. In the coming years, the section is in a position to fully benefit from the nationwide push to the digitalization of health data. Having access to a dense network of collaborating centers, the section can be a key player in the domain of digital oncology.