Annual report 2019

SAKK
WE BRING PROGRESS TO CANCER CARE

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2019: A Year of Changes

Dear Friends and Colleagues,
2019 was a very successful transition year. We not only maintained nearly all our record figures from 2018 but also included more patients than ever before in trials in our core area of interventional trials. This represents a great success for the members and the SAKK Coordinating Center.

Yet 2019 was also marked by some major changes at the Coordinating Center. Dr. Peter Durrer managed SAKK until August 2019 as Interim CEO. He did an outstanding job, successfully steering his team through stormy waters. PD Dr. Martin Reist took over the helm in August.

There were also a number of changes to the composition of the SAKK Board. Prof. Dr. med. Viviane Hess stood down as vice president, leaving a gap that was not easy to fill. Viviane Hess contributed significantly to the positive changes at SAKK, and we would like to take this opportunity to thank her once again for her work. We hope that she will continue to actively support SAKK in the future. PD Dr. med. Dr. phil. Sacha Rothschild was elected as a new member of the Board in her place, and Prof. Dr. med. Miklos Pless took over as vice president.

In 2019 the course was also set for a new way of working in the SAKK Board. Starting in 2020, the Board will convene in the form of a Scientific Committee and a Strategic Committee. With the two committees, the focus can be sharpened, the work professionalized, and quality further increased.

Despite the considerable efforts involved in making these changes, **three major new projects** were initiated:

1. The nationwide Swiss registry project **SAKK Real World Data** for population-based collection of clinical and molecular patient data, in very close collaboration with the Swiss Personalized Oncology project (Prof. Dr. med. Olivier Michielin) and with Prof. Dr. med. Dieter Köberle and his Onconavigator project. Further initiatives were linked with this structure. The first project, Alpine Tumor Immunology Registry (Alpine TIR) headed by PD Dr. med. Ulf Petrausch, will start in 2020.

2. The Working Groups Molecular Oncology and Immuno-Oncology and the Project Group New Anticancer Treatments were merged to form the new Project Group **Developmental Therapeutics**. We hope that the exploitation of synergies and creation of closer ties between basic and clinical researchers will lead to substantial economies of scale.

3. The new Working Group Cellular Therapies was set up. After 18 months of preparation, the working group began operating in November under the leadership of president Prof. Dr. med. Dr. phil. George Coukos and the three vice presidents PD Dr. med. Antonia Müller, PD Dr. med. Heinz Läubli, and Prof. Dr. med. Dr. phil. Sacha Zeerleder. It is noteworthy that the Swiss Paediatric Oncology Group (SPOG) will appoint a fourth vice president in spring of 2020 and that for the very first time, researching oncologists at SPOG and SAKK will be collaborating in the same working group. Here SAKK will take on an important role in coordination of the research fields, use of infrastructure, and also in patient referrals. The aim is through this high level of networking between the centers of excellence to make Switzerland an important international player for new cell therapy approaches.

All in all, the SAKK network underwent a general realignment in 2019 in personnel and content. One very important aspect is without a doubt also the networking with other organizations such as SCTO (Swiss Clinical Trial Organisation), SPHN (Swiss Personalized Health Network), SNSF (Swiss National Science Foundation), the health insurers, and also with Swissmedic.

In response to diminishing financial and human resources, synergies must be used wherever they exist. We are certainly on a good course here, but further efforts are still required.

In 2020 the current SAKK strategy will be reviewed and realigned as necessary. Key concepts here are greater networking within and outside the organization, enhancement of service quality, and greater employee satisfaction – combined with a healthy financial structure. This will be a major challenge, but this transformation for the future will be possible with the help of a strong team comprising the Board, Executive Board, and professional, dedicated employees and members. We would like to thank all our members and the employees at the SAKK Coordinating Center for their commitment and outstanding work. We are confident that we can look forward to a successful future with you all.

Prof. Dr. med.
Roger von Moos
SAKK President

Prof. Dr. med.
Miklos Pless
SAKK Vice President

PD Dr. Martin Reist
SAKK CEO

March

16th St. Gallen International Breast Cancer Conference (BCC)

The St. Gallen International Breast Cancer Conference took place from March 20–23 in Vienna, Austria. Numerous experts from practically all the globally significant cooperative groups and centers active in basic and clinical research and clinical management of breast cancer presented their latest data. SAKK is an official partner of the conference and was represented by experts in Vienna.

June

SAKK at the ASCO Annual Meeting

The annual meeting of the American Society of Clinical Oncology (ASCO) was held in Chicago from May 31–June 4. An abstract on the SAKK 41/06 trial was accepted for the poster session:

– SAKK 41/06: PD Dr. med. Dieter Köberle/ Dr. med. Dr. phil. Peter Moosmann (gastrointestinal tumors)

Further abstracts on SAKK trails in collaboration with cooperative groups were accepted:

– AGO-OVAR 2.29 (ENGOT-ov34): PD Dr. med. Christian Kurzeder (gynecological tumors)
– DANTE: Dr. med. Alexander Siebenhüner (gastrointestinal tumors)

Chicago in the Mountains

The Chicago in the Mountains meeting was held for the seventh time from June 2–5 and for the first time organized by SAKK. At this intensive postgraduate training event, modern transmission technology was used to make the presentations and discussions taking place at the annual meeting of the ASCO accessible to Swiss oncologists at a mountain hotel in Flüeli-Ranft (Obwalden, Central Switzerland). The content was bundled into 12 virtual meeting sessions and two live links to Chicago. As in previous years, the event was booked out very quickly.

SAKK Semi-Annual Meeting June

The SAKK summer semi-annual meeting took place at the Radisson Blu Hotel in Zurich from June 27–28, tying in with the Swiss Oncology and Hematology Congress (SOHC). SAKK project groups, working groups, and sections met up at the event to discuss and elaborate on proposals for trials. As usual, the meeting offered a variety of training and continuing education opportunities for investigators, clinical research coordinators, and other professionals working in in clinical research.

Public Lectures on "Diagnosed with Sarcoma/ GIST: The Latest Research Findings"

On June 27 during the SAKK semi-annual meeting, the SAKK Patient Advisory Board organized public lectures for the fourth time. Some 30 people attended the event to hear about the latest findings of research on one of the rarest types of cancer – sarcoma/ GIST. Renowned experts in pathology, surgery, and oncology spoke on topics including new therapies, histology and molecular genetics, surgery, and immunotherapy.

September

SAKK Translational Prostate Cancer Young Scientist Meeting

SAKK held the 1st SAKK Translational Prostate Cancer Young Scientist Meeting from September 12–13, 2019.

The aim of this event is to enable young specialists in basic and translational research to network more effectively with clinical researchers and to develop ideas for potential SAKK trials or translational projects relating to planned or ongoing SAKK trials in the field of urogenital tumors. A follow-up meeting is planned for September 2020.

SAKK at ESMO Congress

The annual European Society for Medical Oncology (ESMO) Congress took place from September 27 to October 1 in Barcelona. Four abstracts on SAKK trials for the poster sessions plus one presentation were accepted in 2019:

– SAKK 17/16: Dr. med. Yannis Metaxas, oral presentation (lung cancer)
– SAKK 95/16: Dr. med. Michael Mark, poster display session (supportive care in cancer)
– SAKK 57/16: Dr. med. Antonia Digklia, poster display session (sarcoma)
– DANTE: Dr. med. Alexander Siebenhüner, poster display session (gastrointestinal tumors)

Race for Life

On Sunday, September 8, 2019, SAKK took part in the Race for Life charity bicycle marathon and solidarity festival in Bern for the fourth time in succession. SAKK even had two teams taking part, riding around 850 km and collecting CHF 4,280 in donations. SAKK Racer Team 1 took 2nd place after completing 592 km. Congratulations!

November

SAKK Semi-Annual Meeting November

The SAKK winter semi-annual meeting took place from November 21–22, 2019, as usual at the Marriott Hotel in Zurich. More than 700 participants attended the meetings organized by our project and working groups, sections, and networks to discuss ongoing trials and new research projects.

Public Event on "Colorectal Cancer: The Latest Research Findings for Patients"

Following the success of the public event in June, the SAKK Patient Advisory Board organized another series of lectures and discussion in fall 2019 during the SAKK semi-annual meeting. Some 50 people attended the event held at the Marriott Hotel in Zurich to hear about the latest findings of research on the third most common type of cancer in Switzerland.

Registry Conference

During the semi-annual meeting in November, SAKK organized a workshop on "Oncology Registries: What's Going On in Switzerland?" on November 21 in collaboration with the National Strategy against Cancer (NSK). At the session, the SAKK Real World Data (RWD) project was presented and it was explained how clinical and molecular patient data will be collected throughout Switzerland in the future so that it can be made available for research purposes. A number of projects will be linked to this structure. Three of them – Swiss Personalized Oncology (SPO), Alpine Tumor Immunology Registry (Alpine TIR) and Onconavigator – were presented at the event and the leverage of synergies was discussed.

Young Oncology Academy
Graduates of the Young Oncology Academy (YOA) 2019 gave six fascinating post ESMO/EHA/ESTRO presentations to an audience of experts at the SAKK semi-annual meeting in November, bringing the one-year YOA program to a successful conclusion. We would like to thank this year's mentees and the mentors for their exceptional commitment to the YOA 2019.

Prize awards

SAKK / Amgen Research Grant
The SAKK / Amgen Research Grant 2019, a grant of CHF 50,000, was awarded this year to Dr. med. Silvia Angori and Prof. Dr. med. Peter Schraml for their project on "Addressing the Medical Need for Treatment of Patients with Papillary Renal Cell Carcinoma (pRCC) Type 2."

SAKK / Astellas GU Oncology Award
The SAKK / Astellas GU Oncology Award 2019, a grant of CHF 30,000, went to Dr. med. Laurent Derré at Lausanne University Hospital CHUV for his scientific paper on "Conventional and PD-L1-Expressing Regulatory T Cells are Enriched During BCG Therapy and May Limit its Efficacy."

SAKK / Celgene Life Grant
The SAKK/Celgene Life Grant 2019, a grant of CHF 20,000, was awarded to Dr. med. Matea Pavic for her project on "MR-Guided Adaptive Stereotactic Body Radiotherapy (SBRT) for Pain Control in Metastatic Pancreatic Cancer (mPDAC): A Randomized Phase IIb/III Trial."

GIST Prize
The GIST Group Switzerland, which supports people with gastrointestinal stromal tumors, awarded its science prize for the 10th time. The grant of CHF 10,000 was awarded to Dr. med. Stefanie Jilg and Dr. med. Michael Rassner for their work on "Circulating cKIT and PDGFRA DNA Indicates Disease Activity in Gastrointestinal Stromal Tumor (GIST)."

SAKK & Celgene's "HEM Pioneer" Grant
The "HEM Pioneer" Grant 2019 went to Dr. med. Corinne Widmer at Zurich University Hospital for her project on "Use of Artificial Intelligence in the Fight Against Blood Cancer: Early Detection of Diseased Blood Cells in Blood Smears of Peripheral Blood." The grant is CHF 50,000.

SAKK / Dr. Paul Janssen Fellowship
The SAKK/Dr. Paul Janssen Fellowship 2019, endowed with CHF 30,000, was awarded to Dr. med. Christian Fankhauser at Zurich University Hospital. The award was presented by Prof. Dr. med. Viviane Hess, president of the jury. The research grant allows awardees to gain experience at a renowned oncology research center abroad and to acquire the knowledge necessary to develop and implement high-quality clinical trials.

SAKK / Pfizer Award
The SAKK / Pfizer Award 2019 went to Prof. Dr. med. Walter Weber at University Hospital Basel for his research paper on "Impact of a Surgical Sealing Patch on Lymphatic Drainage After Axillary Dissection for Breast Cancer: The SAKK 23/13 Multicenter Randomized Phase III Trial." The prize of CHF 20,000 honors patient-oriented, practical clinical cancer research.

Project Group Breast Cancer

President: Dr. med. Andreas Müller, Cantonal Hospital Winterthur

In terms of accrual, 2019 was a successful year for the Breast Cancer project group: We managed to put 484 patients on trials. The large majority (472 patients) was included in interventional trials. Two new trials contributed to this result: In 2019, we started the **WISE trial (SAKK 95/17)**, which looks at the effect of a 24-week activity program (monitored by a tracking device) on aromatase-inhibitor induced arthralgia. This trial is especially suitable for smaller centers; 31 Swiss centers are open for accrual and contributed 172 patients in one year. This is even faster than expected.

Also started in 2019 was the **ribociclib trial (SAKK 21/18)**, which looks at the efficacy of a ribociclib-endocrine combination vs. chemotherapy in patients with visceral metastatic breast cancer. As expected in this more complex population, accrual did not have a dynamic start: 10 patients were enrolled, but we are now gaining momentum.

An ongoing major contributor to participation for our group is the **TAXIS trial (SAKK 23/16)**, a Phase III trial with 1,500 patients. This trial will answer the question of whether tailored axillary surgery (a reduced operative intervention) in clinically node-positive breast cancer is non-inferior to a conventional axillary dissection (both followed by radiotherapy). SAKK centers enrolled 108 patients in this trial, and we are joined by Austrian, Hungarian, German, and Italian centers (44 patients).

A further main draw is the **REDUSE trial (SAKK 96/12)**, which investigates the optimal dosing of denosumab in bone metastasis. The Project Group Breast Cancer contributed 118 patients this year.

We are part of the International Breast Cancer Study Group (IBCSG) and the Breast International Group (BIG). However only 5 % of our patients were included in such cooperative group trials. It is a goal for the next years to enhance this part of our activities. This year we opened the **POLAR trial (IBCSG 59-19)**, which looks at adjuvant palbociclib in patients with a resected loco-regional relapse, and we continue to contribute to the **TOUCH-trial (IBCSG 55-17)**, which investigates a chemotherapy-free regimen in elderly patients with Her2-positive breast cancer.

In 2019, there were five **publications** in peer-reviewed journals (two on SAKK trials, three on IBCSG trials), one oral presentation at ESMO Breast Cancer, and two posters at major conferences with researchers from our group.

Project Group Gastrointestinal Cancer

President: PD Dr. med. Dr. phil. Andreas Wicki,
Cantonal Hospital Baselland and University of Basel
Vice president: Dr. med. Alexander Siebenhüner,
Zurich University Hospital

In 2019 the SAKK Project Group Gastrointestinal Cancer (PG GI) again recruited between 60 and 70 patients into trials. This figure is comparable to the previous two years. All four open trials continued to recruit during 2019.

The **SAKK 41/13** trial (adjuvant aspirin in PIK3CA mutations) remains the international pioneer in the use of acetylsalicylic acid in patients with colorectal cancer. Twenty-eight patients were recruited in 2019. The trial is ahead of the British Add-Aspirin trial and the French Aspic trial in terms of patient recruitment.

Prodige 32 is investigating the role of surgery in neoadjuvantly treated esophageal cancer for which a curative approach is possible. The ingenious design of this trial offers participating patients direct added value. This trial also has the potential to modify current practice in oncology.

Both SAKK 41/13 and Prodige 32 are examples of good collaboration between SAKK and other European trial groups. Since the trial landscape is becoming ever more complex in oncology and trials are increasingly available only for small, defined subgroups of cancer, these collaborative efforts are a necessary and sound basis for the success of future generations of trials.

The SAKK 41/14 trial is investigating the role of physical activity in patients with metastatic colorectal cancer who are receiving first-line therapy. This looks at an important clinical question that has remained unanswered up to now. The project group will need to put additional effort into recruitment if it is to meet the stated objectives. The group certainly has the will to succeed.

Recruitment by the PG GI is quite impressive in general terms when viewed against the number of open trials. In terms of the population size and the incidence of gastrointestinal cancers, on the other hand, recruitment is too low. Adjusted for population size, the Working Group for Internal Oncology of the German Cancer Society (AIO) recruits about twice as many trial participants in Germany as the SAKK PG GI does in Switzerland. This is something we will need to work on in the coming years.

The SAKK 41/16 trial is an early-stage trial investigating the neoadjuvant use of regorafenib in rectal cancer. The trial recruited well at the dose-finding stage, and the extension phase was initiated in December 2019.

In addition, the **CIRCULATE trial** is scheduled to open in 2020. Initiated by Prof. Dr. med. Gunnar Folprecht and the AIO, it is a pivotal trial investigating the role of liquid biopsy in colorectal cancer. Led by Dr. med. Thibaud Koessler (HUG), the SAKK PG GI performed a trial run with liquid biopsies in 2019 and is now ready to take part in the Phase III trial.

One slight setback is the delayed activation of **DANTE**. This trial will investigate the role of checkpoint inhibitors in treatable stomach cancer. Now that several (financial and regulatory) obstacles have been overcome, it will be activated in 2020.

As for **publications**, there were two publications with quality-of-life data from the SAKK 40/04 trial, a manuscript on mortality and adverse events in trial 44/00, and a manuscript on the relationship between skeletal muscle mass and toxicity in trial 75/08. The SAKK 41/06 trial was presented at ASCO as part of a meta-analysis, and the subproject SAKK 75/08 was presented at the Scientific Association of Swiss Radiation Oncology (SASRO) Annual Meeting.

Project Group Leukemia

President: Prof. Dr. med. Thomas Pabst,
Inselspital Bern (University Hospital of Bern)
Vice president: Prof. Dr. med. Davide Rossi,
Oncology Institute of Southern Switzerland (IOSI)

The year 2019 was a year of transition for the SAKK Project Group Leukemia (PG LEUK). An entire generation of AML (acute myeloid leukemia) trials was closed in late 2017/2018. As a consequence, there was a significant decrease in accrual activity for open trials in 2019, notably after a number of years with very successful enrollment into AML trials. The PG LEUK thus had no open protocols for young fit AML patients or for elderly AML patients for first-line treatment during 2019.

However, significant work was done in 2019 to prepare the activation of a next generation of AML protocols. For the first time, protocols for young fit AML patients at diagnosis will be based on specific molecular subtypes. Consequently, three different protocols are in the process of activation for first-line treatment in young fit AML patients: **HOVON 150** for AML patients with mutations in IDH1 or IDH2. In addition, the **HOVON 156** protocol for patients with mutated FLT3 is in the process of activation. Finally, the **HOVON 160** protocol for triple-negative AML patients is at a somewhat earlier stage of development. The PG LEUK is therefore hopeful that at the beginning of 2021 three different protocols for AML patients fit for intensive cu-

rative treatment will be opened for first-line treatment. The PG LEUK is convinced that this will offer a unique and attractive agenda for AML patients.

For elderly AML patients, the **HOVON 155** protocol is close to activation, presumably in the middle of 2020. It will study the randomized addition of midostaurin to our standard backbone of decitabine treatment. Again, this will be an attractive trial for elderly unfit AML patients for first-line treatment.

The main contribution to recruitment 2019 by the PG LEUK were the **two trials for patients with chronic lymphocytic leukemia (CLL)**. It is most remarkable that the PG LEUK was able to once again position CLL as a major topic for SAKK trials. The successor trial for the closed CLL-13 trial will be activated early in 2021. This will make it possible to continue the remarkable recruitment of patients with CLL in SAKK trials.

For patients with myelodysplastic syndromes (MDS), the activation of the **MDS Registry / SAKK 33/18 I-CARE** trial is planned for 2020. Finally, the preparations for a first-line protocol (TIPI protocol) for chronic myeloid leukemia (CML) for autumn 2020 were successfully advanced.

The recruitment result 2019 of the PG LEUK group is clearly lower than the results seen in previous years. However, the activation of an entire generation of novel protocols for first-line treatment of patients with (AML) is close to being activated. This represents a major task for the principal investigators, the centers, and the Coordinating Center. We are convinced that 2020 will be a challenging and exciting year for the PG LEUK.

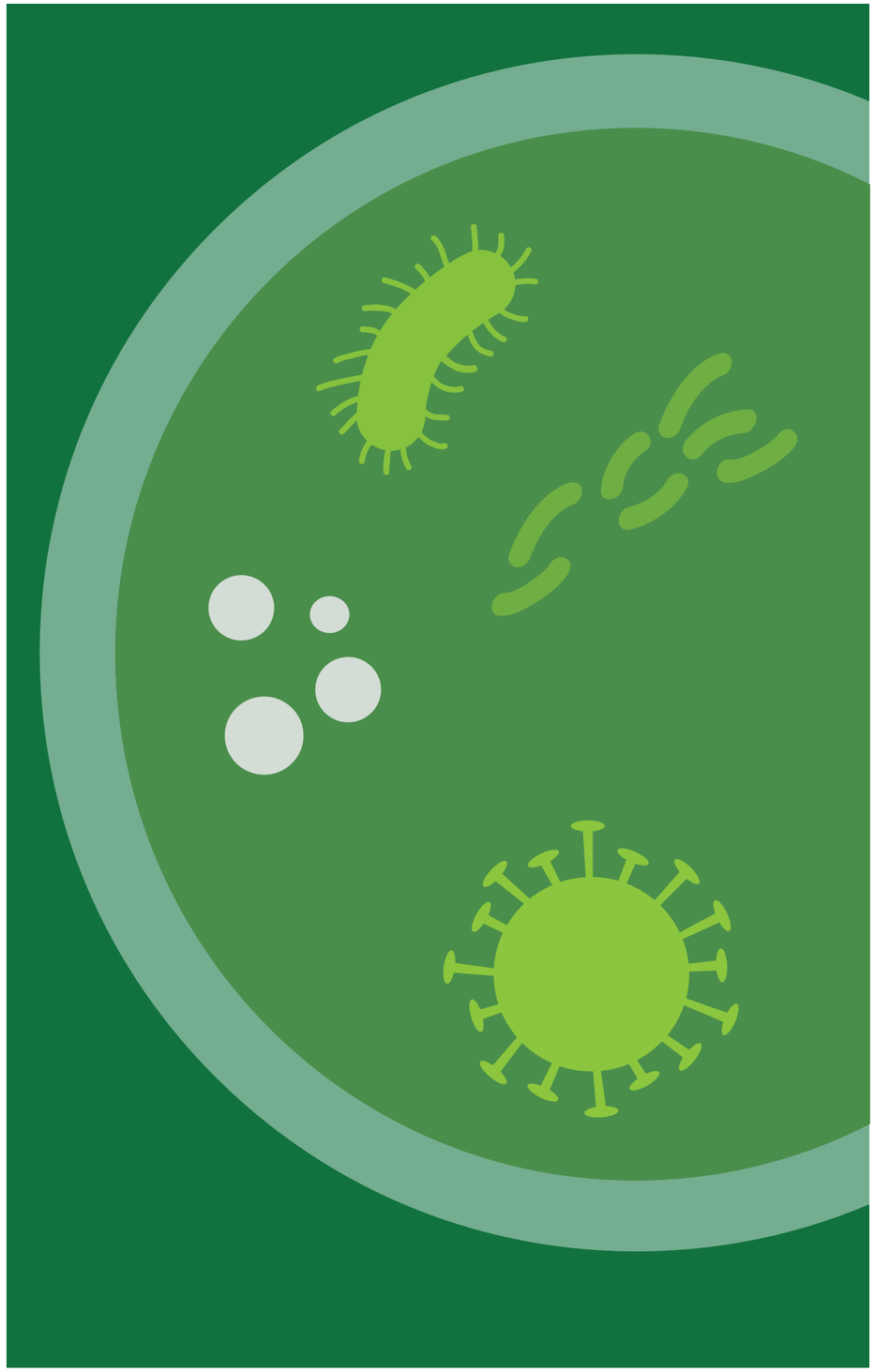
Project Group Lung Cancer

President: Prof. Dr. med. Martin Früh,
Cantonal Hospital St. Gallen
Vice president: Prof. Dr. med. Dr. phil. Solange Peters,
Lausanne University Hospital (CHUV)

SAKK Trials for Lung Cancer/Mesothelioma
In 2019 the Project Group Lung Cancer (PG LU) called a special meeting to discuss its strategy in response to the rapidly changing trial landscape for non-small cell lung cancer (NSCLC). At the meeting, research strategies were developed and the group issued a declaration of intent for research in the area of early stages (NSCLC stage I-III), NSCLC stage IV, and small cell lung cancer/mesothelioma. This discussion of specific ideas for trials was followed by a meeting with interested group members, including younger colleagues, about further implementation of these ideas by concrete planning of projects for the meetings in 2020.

SAKK 16/18, following on from trial **SAKK 16/14** for stage III NSCLC that was closed at the start of the year, was further elaborated in 2019, and recruitment could be started in Q1 2020. As with SAKK 16/14, this is another trimodal treatment concept involving systemic therapy, radiotherapy, and surgery in the age of immunotherapy. The principal investigator is Dr. med. Laetitia Mauti – in line with tradition a younger member of the team.

Further, at the start of 2019 a pooled analysis of 10-year data from the first three SAKK 16 trials for stage III NSCLC was published in the *Journal of Thoracic Oncology*. The paper named a total of 20 co-authors from the group. In 2019, radiomics subprojects of the SAKK 16/00 trial were presented at various congresses, and SAKK 16/08 (multimodal treatment of stage III NSCLC including cetuximab) was published in the *British Journal of Cancer* (first author: PD Dr. med. Alessandra Curioni).



The objective of **SAKK 19/16**, a Phase I trial in which two dose levels of the MEK inhibitor binimetinib were investigated in combination with first-line therapy with cisplatin and pemetrexed in patients with metastatic KRAS-mutated non-small cell lung cancer, was to establish the maximum tolerated dose. The trial was able to complete accrual at four SAKK Phase I centers in Switzerland at the end of 2019 although patient accrual declined as new therapeutic options rapidly became available. KRAS mutations make up the major molecular subgroup, accounting for up to 25 % of patients with non-squamous NSCLC, and the results of this trial will be presented in 2020. Gratifyingly, 2019 saw the successful publication in *Lung Cancer Journal* of a Swiss cohort study on patients with EGRF mutation treated with osimertinib, specifically examining the pattern of recurrence in these patients. The project was headed by Dr. med. Sabine Schmid in collaboration with a large number of group members at a wide range of Swiss centers.

SAKK 17/16, a Phase II trial for mesothelioma, investigating lurbinectedin in second-line therapy, was the topic of an oral presentation at ESMO 2019, and the manuscript reporting the promising results is currently under review at *Annals of Oncology*. The first author of the project is Dr. med. Yannis Metaxas in Chur, another younger member of our group. Further, a subproject of **SAKK 17/04** was published by Dr. sc. nat. Jelena Kresoja-Rakic in *Noncoding RNA*. The efficacy of pembrolizumab in a cohort of mesothelioma patients was published in the *Journal of Thoracic Oncology* in collaboration with Australian centers, led by two young colleagues from our group (Dr. med. Yannis Metaxas and Dr. med. Laetitia Mauti). PD Dr. med. Oliver Riesterer was successful in publishing a subproject of SAKK 17/04 on patterns of recurrence after multimodal treatment of mesothelioma including radiotherapy in the journal *Radiotherapy and Oncology*.

SAKK 19/17, a single-arm Phase II trial run by Dr. med. Michael Mark in Chur with chemotherapy-naive NSCLC patients with PD-L1 positive tumors (> 25 %) who are in poor general condition (PS2) recruited very rapidly in 2019. A safety analysis subsequently led to an interim halt to recruitment, but recruitment is still scheduled for completion during 2020.

We are pleased to report that in 2019 a trial for small cell lung cancer (SCLC), **SAKK 15/19**, was also approved by the SAKK Board. This first-line trial will further investigate the value of chest radiotherapy in metastatic SCLC in the age of first-line chemoimmunotherapy. This Phase II trial is scheduled to open in 2020. A Swiss cohort study on the use of immunotherapy in patients with SCLC by Dr. med. Sabine Schmid and Dr. med. Laetitia Mauti was presented at the World Conference on Lung Cancer (WCLC) 2019 and is currently in print at the journal *Cancer Immunology, Immunotherapy*.

In the age of targeted therapies, the group successfully initiated **SAKK 19/18**, a Phase II trial in patients with previously treated squamous cell carcinoma and FGFR mRNA overexpression. The oral FGFR inhibitor rogaratinib in patients with no alternative standard therapy options is being investigated in this selected group. The project is being led by a young colleague in Geneva (Dr. med. Alfredo Addeo).

Collaborative Trials on Thoracic Cancers

Successful collaboration with the European Thoracic Oncology Platform (ETOP) and the European Organization for Research and Treatment of Cancer (EORTC) continued in 2019. The collaboration is ongoing mainly in the context of major Phase III trials and in niche trials for rare indications.

The potential authorization trial (**PEARLS**) is an adjuvant placebo-controlled trial to evaluate pembrolizumab in resected non-small cell lung cancer. The recruitment phase was completed in autumn 2019 with a very good level of participation by Swiss centers. The **ETOP PROMISE-meso** trial, the second trial in patients with mesothelioma after the lurbinectedin trial, was presented in an oral session at ESMO 2019. Recruitment into **ETOP BOOSTER**, a randomized trial investigating the role of bevacizumab and osimertinib in patients with a positive T790M mutation after first- or second-generation EGFR tyrosine kinase inhibitors, was completed in 2019 with a good level of recruitment at the participating Swiss centers. A subproject of the preceding trial (**ETOP BELIEF**) was published in the *Journal of Thoracic Oncology* in 2019; the trial demonstrated the negative prognostic effect of identifying the EGFR mutation in blood at initial presentation of the disease or at progression.

ETOP ALERT (alectinib in RET-positive lung cancer), which is still open, is a further protocol for rare cancers of the chest. Further collaborative trials with EORTC and ETOP that opened in 2019 are: **EORTC HALT** (a randomized trial investigating the role of radiotherapy in patients with oncogene-dependent lung cancer and oligoprogression on tyrosine kinase inhibitors) and **ETOP 14-18 CHESS** (multimodal therapy of oligo-metastatic non-small cell lung cancer at selected centers). **ETOP 13-18 BEAT-meso** (a randomized Phase III trial with chemotherapy and bevacizumab and atezolizumab in mesothelioma) was opened as a follow-up trial to the ETOP PROMISE trial, which is recruiting very successfully. ETOP 13-18 BEAT-meso is already recruiting rapidly at several centers in Switzerland.

A new and successful collaboration with members of a Scandinavian trial group also began in 2019 with the **ACHILES** trial, a randomized trial investigating the value of additive atezolizumab following completion of definitive radiochemotherapy in localized SCLC. The trial will open throughout Switzerland in Q1 2020.

Although overall recruitment figures were slightly lower in 2019 than in the previous year (the total decreased to 75 patients, partly because 'only' 6 trials were open during a short period of time), 2019 was a successful year on the whole, given the numerous publications/presentations and the many new and interesting (and, in particular, pragmatic) projects that are being developed.

Project Group Lymphoma

President: PD Dr. med. Urban Novak,
Inselspital Bern (University Hospital of Bern)
Vice president: Prof. Dr. med. Francesco Bertoni,
Oncology Institute of Southern Switzerland (IOSI)

In 2019, a total of 167 patients in 23 sites in Switzerland (including all university hospitals in Switzerland) and additional sites abroad were included in 12 clinical trials. The true significance of this achievement can be seen in relation to the total number of patients in SAKK trials (1,335): The number of participants has increased steadily in recent years. This is particularly impressive in view of the fact that lymphomas account for only 5 % of all cancer patients in Switzerland. The contribution of the Project Group Lymphoma (PG LYMPH) of more than 12 % of the SAKK patients all in academic interventional trials is even more impressive considering that this included patients with rare diseases such as mantle cell lymphoma, CNS lymphoma in elderly frail patients, primary mediastinal lymphoma, and Burkitt lymphoma, which together are diagnosed in fewer than 150 patients a year in Switzerland. Along with the existing referrals, this is clear proof of the committed efforts of the whole project group. In addition, we are confident that with proactive interventions, we will soon reach the target accrual for the **SAKK 36/13** and **SAKK 35/14** trials and, with determined academic spirit, also for the OptiPOM trial (**SAKK 39/16**).

The scientific output of the group is also outstanding: It authored 6 of the 17 abstracts at prestigious meetings in the lymphoma field and 5 of the 35 accepted manuscripts on trials with SAKK contributions. Three of these are within the top five (**REMoDL-B**, **HD16**, and **SAKK 35/10**), whereby the publication with the highest impact for SAKK in 2019 deserves special mention. (REMoDL-B in *Lancet Oncology*).

Having reached the target recruitment, we closed two randomized trials in 2019: **IELSG-43** (role of consolidation for primary CNS in fit patients) and **IELSG-37** (consolidation radiotherapy). We opened four new trials: **SAKK 66/18**, a Phase I trial with copanlisib and venetoclax for relapsed lymphomas (based on preclinical work done in a SAKK group member's lab), **IELSG-45** for patients with CNS lymphoma not fit for intensive treatments, **IELSG-47**, a first line trial for marginal zone lymphoma, and EMCL Registry, a first registry for patients with relapsed mantle cell lymphomas.

To have a portfolio with trials for the most frequent entities, we worked hard to get the Phase II of the successful **SAKK 35/15** trial and to finally open **RADAR**, an international academic trial for early stage Hodgkin's disease. In December 2019 a kick-off meeting was held for **SAKK 38/19**, an international trial on first-line treatment of diffuse large B cell lymphoma (DLBCL) with a very competitive design that incorporates the latest technical advances.

As the first Swiss patients received CAR-T cells in January 2019, various members of the Project Group Lymphoma will actively be involved in the newly created Working Group Cellular Therapies and will contribute their experiences with these exciting new therapeutic options for lymphoma patients.

Last but not least, we will do our very best to actively engage our three Young Oncology Academy members in the activities of our group!

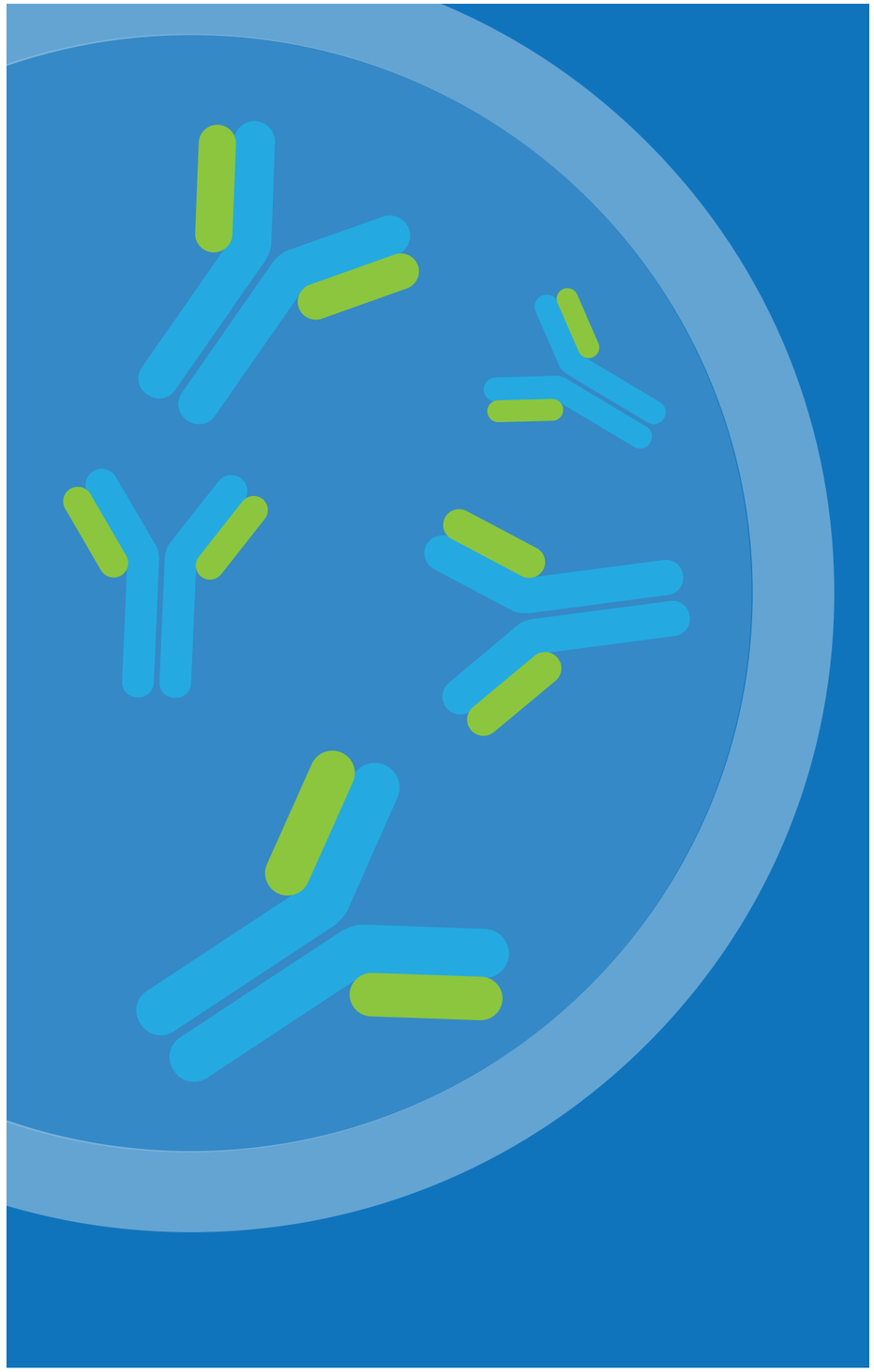
Project Group New Anticancer Treatments

President: Prof. Dr. med. Markus Jörger,
Cantonal Hospital St. Gallen
Vice president: PD Dr. med. Anastasios Stathis,
Oncology Institute of Southern Switzerland (IOSI)

The SAKK Project Group New Anticancer Treatments (PG NAT) will be undergoing some changes in the near future. On November 22, the members of PG NAT and the working groups Immuno-Oncology (IO) and Molecular Oncology (MO) decided to merge and become the **new Project Group Developmental Therapeutics (PG DT)**. This merger will allow us to make optimal use of the expertise of all members, to have strong trials in the immunotherapy and non-immunotherapy fields, potential combinations between the two, and strong translational programs. By that, the new PG DT will have a broadened focus on innovation in oncology as well as an increased member base. PG DT will be led by the current president and a vice president up to 2022. They will be supported by two additional vice presidents with a focus on IO and on MO, who will be elected in May 2020.

2019 was again an eventful year for the group: The **SAKK 66/18** copanlisib/venetoclax lymphoma trial opened in September. SAKK 66/18 investigates the combination of the intravenous PI3Kδ inhibitor copanlisib with the BCL2 inhibitor venetoclax in patients with non-Hodgkin's lymphoma. The first two patients have already been treated.

PG DT currently supports the recruiting for eight ongoing Phase I(/II) clinical trials in a broad range of tumor entities including lung cancer (SAKK 19/16), rectal cancer (SAKK 41/16), head-and-neck squamous cell carcinomas (SAKK 11/16), and soft-tissue sarcomas (SAKK 57/16). The recruiting phase was completed in May 2019 for **SAKK 35/15** on the combination of the BCL2-inhibitor venetoclax and the anti-CD20 monoclonal antibody obinutuzumab in patients with treatment-naïve follicular lymphoma, and a follow-up Phase II trial is currently being negotiated with industry partners. Of special note,



SAKK 67/15 with the tumor checkpoint controller BAL-101553 (lisavanbulin) was put on hold as of December 11, 2019. More than half of the expected expansion cohorts in glioblastoma and ovarian cancer were accrued, and there was activity in both tumor entities. **SAKK 67/15** is expected to be reactivated in summer 2020 with a biomarker-led enrichment design and using the oral formulation of lisavanbulin. Phase I of SAKK 67/15 was published in the journal *New Investigational Drugs*. SAKK 65/16 with Talidox, a new liposomal formulation of doxorubicin, is close to defining the recommended Phase II dose. Roughly 60 patients were enrolled in trials of the PG DT in 2019, which is a substantial increase compared to previous years.

In the future, our group will work intensively on our pipeline of more advanced trials, whereby at least 3 clinical trials should be activated in 2020. PG DT is expected to open **SAKK 66/17**, a trial that investigates the combination of laser-assisted thermal tumor ablation followed by intratumoral n-dihydrogalactochitosan (IP-001) in patients with advanced solid tumors, a Phase I trial of a new docetaxel micellar formulation for patients with castration-resistant prostate cancer, and **SAKK 17/18**, a combination of atezolizumab and gemcitabine in patients with advanced NSCLC or mesothelioma.

Project Group Urogenital Tumors

President: PD Dr. med. Aurelius Omlin,
Cantonal Hospital St. Gallen
Vice president: Dr. med. Alexandros Papachristofilou,
University Hospital Basel

2019 was another successful year for the Project Group Urogenital Cancer (PG URO), with high recruitment rates. A total of 398 patients were recruited into 11 open trials in 2019, 124 patients into the SAKK 63/12 biobank trial and the others into classic interventional drug trials. The SAKK PG URO portfolio comprises trials for four different tumor entities.

Trial **SAKK 06/17** for localized muscle-invasive bladder cancer, investigating neoadjuvant therapy with cisplatin, gemcitabine, and durvalumab, was successfully concluded in 2019 with 61 enrolled patients. The first interim results were submitted for a presentation at the 2020 Genitourinary Cancers Symposium organized by the American Society of Clinical Oncology (ASCO GU). A follow-on project SAKK 06/19 is in development and can hopefully be opened in 2020.

Trial **SAKK 01/18** for germ cell tumors was opened in 2019 as a follow-on project to the successfully concluded SAKK 01/10 trial. Initial findings will be presented as a poster at ASCO GU 2020. Patients with stage IIA/B seminoma will be recruited into the new project; reduction of the radiation volume will be investigated in stage IIA, intensification of chemotherapy in combination with radiotherapy in stage IIB. Academic trials are of great importance in this situation so that further progress can be made in the treatment of a curable metastatic disease.

Trial **SAKK 07/17** for renal cell carcinoma was able to recruit the planned number of patients unexpectedly rapidly in 2019. It was possible to negotiate a further expansion of this project, which has an extensive translational research component, allowing the recruitment of a further 35 patients.

Prostate cancer remains the group's primary focus, with a total of eight trials. They cover a very wide spectrum, and patients at practically all stages of the disease (localized, salvage with increased PSA, metastatic hormone-sensitive, metastatic castration-resistant) can be treated in one of our SAKK trials. Important data from the **STAMPEDE** trial, performed in collaboration with the Medical Research Council (MRC), was published in 2019 in a paper co-authored by members of the SAKK PG URO. However, recruitment into the STAMPEDE trial is well below expectations in terms of the possible range of patients who could be recruited and the importance of the STAMPEDE trial, which has already contributed to the establishment of several new therapeutic standards for prostate cancer. Continued collaboration in 2020 will only be worthwhile if the SAKK PG URO members start actively recruiting patients into the trial again.

The **SAKK 09/18** trial, which is recruiting patients with localized prostate cancer (intermediate or high-risk) and randomizing them to pelvic lymphadenectomy or not, was opened in 2019. Fourteen patients were recruited already in the first few months. A total of 900 patients are needed for this trial, and the PG URO members and international collaborations will have to make a major effort to recruit the required number of patients within the projected time period.

The **PEACE-4** trial was also opened in 2019. This trial seeks to establish whether the addition of the antithrombotic acetylsalicylic acid and/or the statin atorvastatin to standard CRPC therapy can increase survival times. Alongside STAMPEDE trial and SAKK 08/14 trial, which are investigating the effect of metformin in the hormone-sensitive and castration-resistant situation, PEACE-4 will now look at the additional benefit (and any possible risks) of adding aspirin and/or a statin to the standard therapy. It is important to note that the standard therapy can be given independently of the trial and is not affected by it. Men with M0-CRPC can also be recruited into the PEACE-4 trial. Patients taking a statin or aspirin daily or who have taken either in the previous 6 months unfortunately cannot be recruited. As an academic trial, this project relies on men with advanced castration-resistant prostate cancer being informed about the possibility of taking part in this trial.

Trials **SAKK 08/14** (enzalutamide plus/minus metformin as first-line therapy in castration-resistant prostate cancer), **SAKK 08/15** (salvage radiotherapy with increased PSA after local therapy plus/minus metformin), and **SAKK 08/16** (maintenance therapy with enzalutamide or placebo after chemotherapy with taxanes) continued recruiting in 2019 and, largely thanks to centers abroad (SAKK 08/15 and SAKK 08/16), took a major step towards completing their envisaged patient recruitment.

The first interim safety findings of trial **SAKK 96/12** (denosumab every 4 weeks versus every 12 weeks in prostate cancer and breast cancer) were presented at ASCO GU 2019. Of the planned 1,380 patients, 998 have already been recruited.

The first **SAKK Translational Prostate Cancer Young Scientist Meeting** was held in September 2019 on the Uetliberg near Zurich. The aim of this initiative is to better network researchers working in basic and translational urogenital research with researchers active in clinical research, and to develop ideas for potential SAKK trials or translational projects associated with planned or ongoing SAKK PG URO trials. A follow-up meeting is already planned for September 2020.

The following **goals** have been set for 2020:
- Further active recruitment into all SAKK PG URO trials, in particular with a focus on even better recruitment in the prostate cancer trials.
- Continuing European and international collaboration in order to conclude trials successfully and within the projected time frame.
- Motivation of young researchers to become active in the SAKK PG URO with their own projects or ideas for translational subprojects.

Working Group CNS Tumors

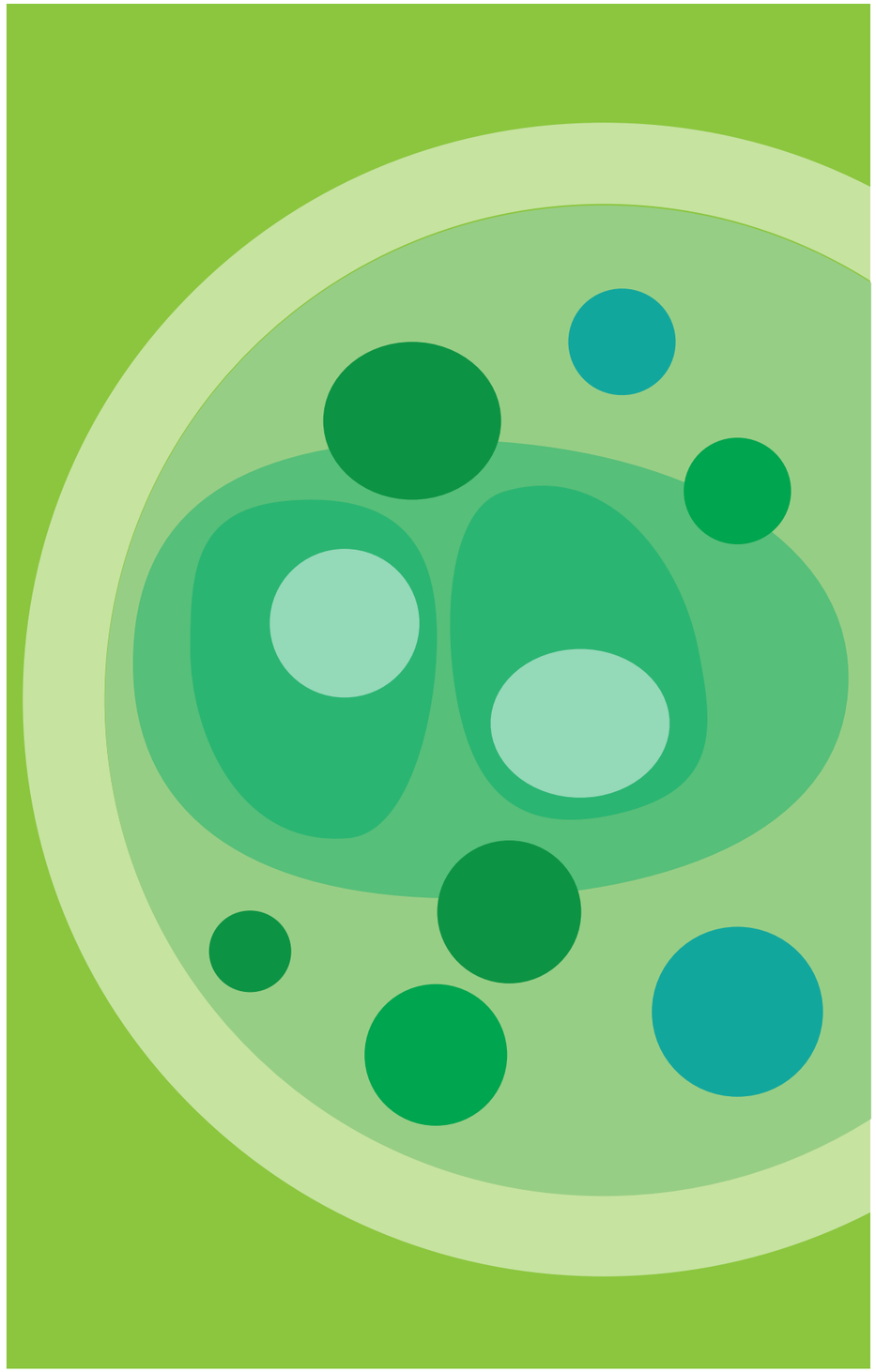
President: Dr. med. Patrick Roth, Zurich University Hospital
Vice president: Prof. Dr. med. Philippe Schucht,
Inselspital Bern (University Hospital of Bern)

Tumors in the central nervous system (CNS) remain a particular therapeutic challenge in the field of clinical oncology. The interdisciplinary Working Group CNS Tumors aims at expanding and strengthening the neuro-oncological community in Switzerland. Providing patients with brain tumors access to novel treatment options is the ultimate goal of the group within the SAKK network. The members of the group are involved in various clinical and scientific activities in Switzerland and beyond.

Many group members are involved in national and international research activities in academic groups as well as jointly with industry partners. In 2019, the **SAKK 67/15** trial for patients with recurrent glioblastoma was open at several Swiss sites. Enrollment is ongoing. Further, several SAKK centers are participating in the randomized Phase III **EORTC 1709** trial, which is running outside of the SAKK network and explores the activity of marizomib, a novel brain-penetrant proteasome inhibitor, in patients with newly diagnosed glioblastoma. It is expected that patient accrual will be completed in 2020.

The members of the working group have discussed the role of the group within SAKK on several occasions and understand that CNS tumors have not been considered a topic of high priority by the Board in the past. Nevertheless, the members of the group continue to develop new clinical trial protocols and initiatives hoping that they can be realized under the umbrella of SAKK in the near future.

In 2019, several members of the group developed a consensus manuscript on the management of adult patients with diffuse gliomas in Switzerland, which has been submitted for publication. Also, one of the ongoing scientific projects of the group aims at establishing driving guidelines for patients with brain tumors (“fitness to drive”).



Working Group Head and Neck Cancer

President: Dr. med. Marco Siano,
Hôpital Riviera-Chablais Vaud-Valais, Vevey
Vice president: Prof. Dr. med. Christian Simon,
Lausanne University Hospital (CHUV)

In 2019 the MaxiVAX trial (SAKK 11/16) was opened, the promised recruitment into the "best of" trial SAKK 10/16 was achieved, and the Patterns of Care trials were published.

The **SAKK 11/16** trial is investigating whether the immunotherapy with MVX-ONCO-1 is effective, safe, and well tolerated in in patients with advanced head and neck squamous cell carcinoma. This immunotherapy consists of dead tumor cells from the patient and genetically modified cells in a capsule being injected subcutaneously. The trial is being run in collaboration with the biotech company MaxiVAX SA, which won the CTI Swiss Medtech Award for this innovative vaccine project at the Swiss Medtech Day in June 2017. After an initial delay, recruitment was continued in Geneva and was started at the other centers. We hope to be able to recruit the required patients in 2020.

The 'best of' trial **SAKK 10/16** is recruiting as planned, and by the end of 2021 the patients promised by the Swiss and international centers are expected to have been recruited. A trial amendment now allows not only patients with oropharyngeal cancer but also patients with cancer in other parts of the head and neck to be recruited. This is an important trial for the working group to show that the formalized collaboration with EORTC is being put into practice and to ensure that SAKK will be considered as a partner for future trials.

Further projects are currently being evaluated. Among them is the **follow-up trial** (investigator Prof. Dr. med. Roland Giger, Inselspital Bern) that will be presented to the SAKK Board for approval in 2020 and an **induction chemoimmunotherapy trial** (European Larynx Organ Preservation Study) that is currently being elaborated.

The **Patterns of Care trials** (investigator Dr. med. Olgun Elicin, Inselspital Bern) were published in 2019. Under the stewardship of SAKK, and with the involvement of the participating SAKK centers, the trial was split and published as four smaller trials. This made it possible to highlight the diversity of therapy and the reality of head and neck cancer in Switzerland, something that provides important indicators for the implementation of future projects. All the disciplines took part in this trial, resulting in a lively and productive interdisciplinary exchange.

Working Group Immuno-Oncology

President: Prof. Dr. med. Dr. phil. George Coukos,
Lausanne University Hospital (CHUV), University of Lausanne
and Ludwig Institute for Cancer Research, Lausanne
Vice president: PD Dr. med. Ulf Petrausch, OnkoZentrum Zurich;
Dr. med. Alexandre Theocharides, Zurich University Hospital;
Prof. Dr. med. Alfred Zippelius, University Hospital Basel

The Working Group Immuno-Oncology (WG IO) aims at fostering partnerships with universities, startups, and industry to combine local expertise in translational research in cancer immunotherapy with the advantages in patient recruitment provided by collaboration with SAKK.

In this regard, the group works in close collaboration with the SAKK Project Group New Anticancer Treatments, which already draws on a dynamic network of Phase I and accredited First-in-Human Phase I trial sites.

Trial Highlights
The Alpine Tumor Immunology Registry is currently open at six Swiss and Austrian sites, with more than 300 patients retrospectively included, and represents a frontrunner in the field of data collection. **SAKK 06/17**, designed jointly by the WG IO and Project Group Urogenital Tumors (PG URO), combining immunochemotherapy for bladder cancer, completed recruitment ahead of schedule. **SAKK 17/18**, combining gemcitabine and nivolumab in advanced NSCLC and mesothelioma patients, is aiming for activation in Q3 2020. Several further innovative IO combinations are in development.

Establishing a SAKK Working Group Cellular Therapies
2019 has seen rapid advances in the use of T-cell therapies in cancer therapy, with clinical uptake of approved products and vigorous efforts to further investigate the potential of this novel kind of immunotherapy in both hematological and solid tumors. Nationwide coordination has been deemed essential in the areas of research, manufacturing, exchange with regulatory authorities, and monitoring results; to this end, a Working Group Cellular Therapies was created, focusing on academic research, innovative cellular therapies, and collaborative research with pharmaceutical companies.

Future Perspective
PG New Anticancer Treatments, WG Immuno-Oncology, and WG Molecular Oncology will merge under the umbrella of the **new Project Group Developmental Therapeutics (PG DT)** and hold common meetings to further streamline efficacy in trial development.

Working Group Molecular Oncology

President up to June 2019:
PD Dr. med. Dr. phil. Sacha Rothschild, University Hospital Basel
Vice president: PD Dr. med. Dr. phil. Tobias Grob,
University of Bern

2019 was the third year in which the Working Group Molecular Oncology operated. The group is an interdisciplinary network of medical oncologists, pathologists, molecular biologists, and hematologists.

Personalized oncology aims to offer the best possible cancer therapy for each patient based on rational criteria and an in-depth analysis of the tumor. 'Best possible' refers to the relationship between efficacy and adverse effects, and also the reciprocal relationships between multiple therapy options. The objective of the SAKK **Onconavigator** project is to advance personalized oncology in Switzerland within a broad context. It comprises a national registry of patients with advanced solid cancers of all types. This registry will be part of the Real World Data (RWD) database initiated by SAKK. A next generation sequencing (NGS) tumor analysis must be performed before patients can be included. This can be done locally and must include at least a standard panel. The therapy decision is solely the responsibility of the oncologist and the patient. The treating oncologist can recommend a targeted therapy or a conventional therapy to the patient if NGS sequencing identifies a treatable modification. The oncologist can consult a molecular tumor board if required; on request, this board develops recommendations for personalized therapy based on the genomic testing. The registry records all drug therapies, i.e., all targeted and all non-targeted therapies. The Onconavigator project made further progress last year, and the trial is scheduled to begin in 2020.

Starting in 2020, the Working Group Molecular Oncology will form the **Project Group Developmental Therapeutics** with the Working Group Immuno-Oncology and the Project Group New Anticancer Treatments, and they will hold joint meetings.

Working Group Sarcoma

President: Dr. med. Attila Kollàr,
Inselspital Bern (University Hospital of Bern)

The great enthusiasm and dedication of our small research group is reflected in the sarcoma trials mentioned below that are either ongoing or in preparation. Three clinical sarcoma trials were open in Switzerland in 2019.

The highlight of the year was the presentation of the Phase I results of **SAKK 57/16 (NAPAGE)** at the ESMO Congress in Barcelona. The therapy was tolerated well in this national, multicenter, open, single-arm Phase Ib/IIa trial to investigate nab-paclitaxel in combination with gemcitabine in advanced soft tissue sarcoma, and the dosage for the now ongoing Phase II trial was defined. Recruitment into the Phase II trial is very satisfactory. Around half of the planned patients were already recruited in the first year.

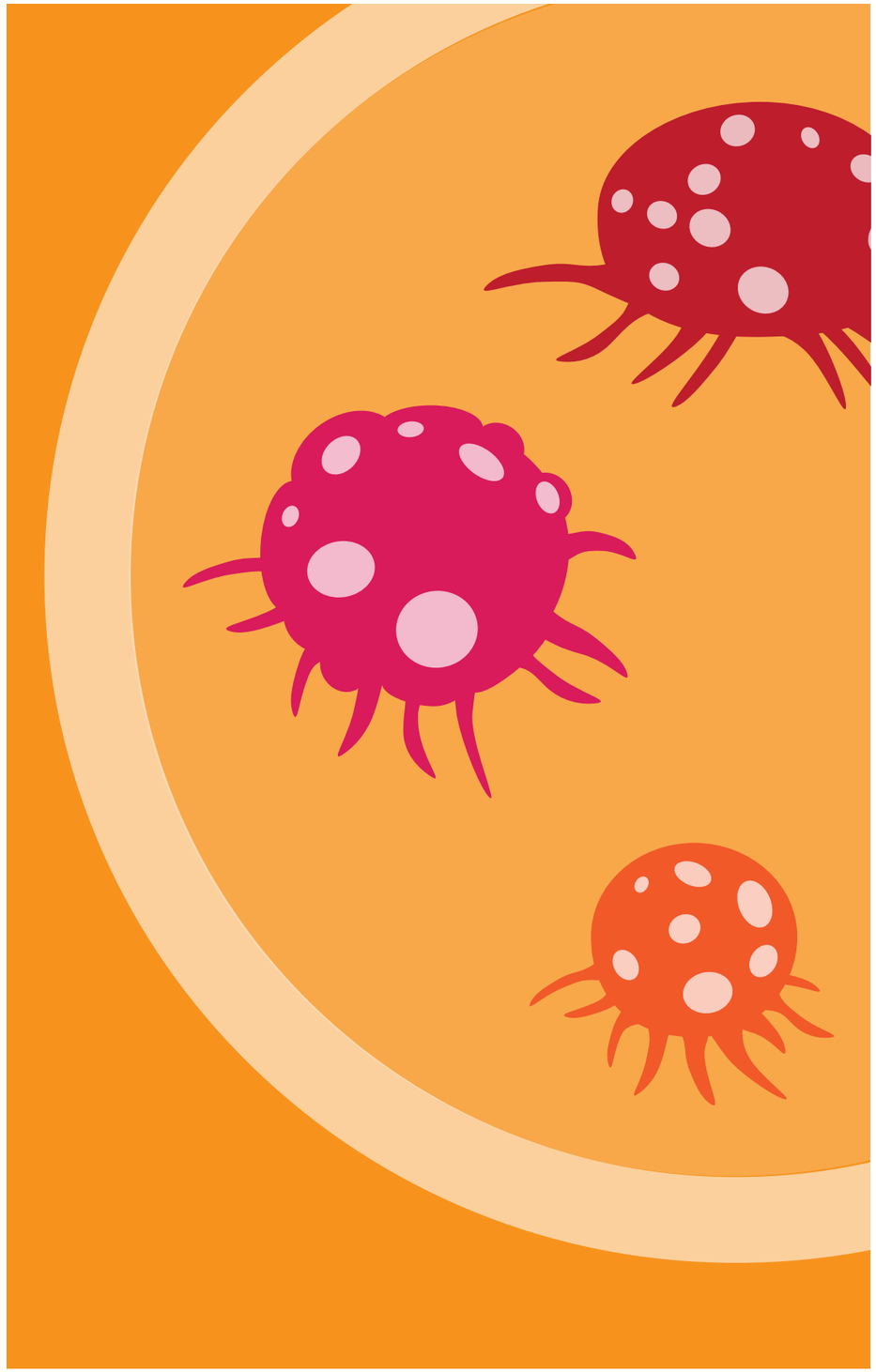
The **EURO EWING 2012** trial is an international, randomized, controlled trial for the treatment of newly diagnosed tumors from the Ewing's sarcoma family. Recruitment into the trial was closed in the spring after it had been running for a short time at the Swiss sarcoma centers and following communication of the results of a planned interim analysis. That data shows improved survival associated with chemotherapy using the VDC/IE regimen compared with VIDE-based chemotherapy.

The **PazoQoL or GISG 11** trial, on the other hand, was opened with major support from SAKK. In this multicenter Phase III trial, which per se compares palliative systemic therapy in the form of pazopanib with a freely chosen palliative chemotherapy, patients' quality of life is studied using patient reported outcomes. The first patients have already been recruited into this trial.

The following trials are in the planning stage after lively discussion during the SAKK meetings.

- **STRASS-2** is an international, multicenter, randomized Phase III trial investigating the efficacy of neoadjuvant chemotherapy followed by tumor resection compared with tumor resection alone in retroperitoneal sarcoma. The SAKK Board approved the activation of this trial initiated by EORTC on the condition that it received adequate funding. The trial is expected to open in spring/ summer of 2020.
- Although immuno-oncological approaches to the therapy of sarcomas have generally shown modest efficacy to date, our group is seeking to initiate a clinical trial in this field with the aim of defining and analyzing sub-entities that could benefit from immunotherapy-based treatment. The first protocol proposal, "Treatment sequence of doxorubicin followed by pembrolizumab combined with axitinib or vice versa in locally advanced/ metastatic soft tissue sarcoma subtypes: a randomized Phase II or III trial" (**DIID-Trial**), is being evaluated.
- Parallel to that, another protocol is being worked on: "Neoadjuvant HYPErthermia, radiotherapy and immune CHECKpoint blockade in high-grade soft tissue sarcoma (**HYPE-RT-CHECK**): a proposal for a Phase I/II trial." The trial will investigate a combination of radiotherapy intended to be neoadjuvant with hyperthermia and immunotherapy in soft tissue sarcoma.

Sarcoma trials will continue to be an area in which initiation and participation must be pursued carefully in Switzerland because these tumors are so heterogeneous and rare.



Working Group Supportive Care and Palliative Cancer Care

President: Prof. Dr. rer. med. Manuela Eicher,
Lausanne University Hospital (CHUV) and University of Lausanne
Vice presidents: Dr. phil. I Karin Ribi,
International Breast Cancer Study Group (IBCSG),
Prof. Dr. med. Claudia Witt, Zurich University Hospital

The field of supportive and palliative cancer care offers a number of potential topics including supportive and palliative care interventions, geriatric oncology, psycho-oncology, and cancer rehabilitation. The Working Group for Supportive Care and Palliative Cancer Care discussed several trial ideas in 2019. One trial proposal is a randomized controlled trial investigating the effect of a single dose ferric carboxymaltose injection for solid tumor patients with functional iron deficiency on quality of life. This trial will be further developed based on comments received from the SAKK Board. The group also discussed early trial ideas addressing objective methods of prognostication for tumor-directed palliative treatment and a multimodal cachexia prevention in patients with advanced pancreatic cancer. Results of **SAKK 95/16**, a cross-sectional trial describing patterns of care in Switzerland for patients with metastatic bone disease in solid tumors, were presented at ESMO 2019, and a manuscript was published in December 2019. Further manuscripts presenting data on patient-reported outcomes and pharmaco-economics are in planning. In November 2019, the group reelected Prof. Dr. med. Manuela Eicher as president and Dr. phil. I Karin Ribi as vice president. Prof. Dr. med. Claudia Witt at University Hospital Zurich was newly elected as vice president.

Section Network for Cancer Predisposition Testing and Counseling

President: PD Dr. med. Sheila Unger,
Lausanne University Hospital (CHUV)
Vice president: Dr. med. Salome Riniker,
Cantonal Hospital St. Gallen

In 2019, the Network for Cancer Predisposition Testing and Counseling (CPTC) saw a significant increase in its membership, with now almost 100 active members. One of our strongest assets is that our network is a truly multidisciplinary group comprised of oncologists, gynecologists, geneticists, biologists, nurses, and genetic counselors. Being multidisciplinary allows us to address the field of hereditary predisposition from many different clinical perspectives. It also allows us to be recognized as the relevant partner by both the government and the health insurances.

The basic course in genetic counseling for cancer syndromes, which takes place annually in March in St. Gallen, is very popular. Since 2017 this has been carried out under the patronage of SAKK. The program is updated annually and adapted to Swiss guidelines. The organizers and many speakers are members of the CPTC network. The course is aimed at doctors and other medical professionals who want to develop their counseling skills, and it is a basic prerequisite for being able to offer genetic counseling in Switzerland for cancer syndromes. The 2020 course is already full with a waiting list. In addition to this course, we have instituted a yearly educational session, and the session in November 2019 was a particular success. The room was full to capacity and more (overflow into the corridor) for a session on polygenic risk scores.

The counseling guide for genetic counseling for hereditary breast and ovarian cancer syndrome (HBOC) developed by the network for CPTC is widely used and is available electronically on the SAKK homepage. The accompanying patient information brochure has now been produced in conjunction with the Swiss Cancer League.

A monthly web conference to discuss family trees, clarification steps, and test results for hereditary tumor syndromes was launched in September 2019. In 2020, it will also include a journal club.

A revision written by the CPTC group of Article 12d d of the DHA Ordinance on Compulsory Health Insurance Benefits has received formal approval from the Swiss societies for gynecologists, senologists, and geneticists. It has now been submitted to the Federal Office of Public Health (FOPH/OFSP/BAG) for consideration.

The network for CPTC will continue to work on various projects in 2020, including revising the Swiss guidelines for HBOC tests as a priority and following up on the revision of Article 12d d and f, as well as recommendations for early screening of women with a high risk of breast cancer with and without genetic predisposition.

Section Pathology

President: Prof. Dr. Rupert Langer, University of Bern

The Pathology section sees itself as a diagnostic and scientific platform that aims to offer support particularly in translational research associated with clinical trials. At the same time, it initiates and runs its own projects in close collaboration with the organ-specific SAKK project groups and working groups. It is also involved in the quality assurance in clinical trials regarding pathology diagnoses, compliance with pre-analytical and analytical standards in tissue-based analysis, the application and introduction of new analytical methods, and the establishment, operation, and maintenance of tissue banks. Of note here are the projects led by Prof. Varga, a pathologist in Zurich and a member of the PG Breast Cancer, focusing on the proliferation marker known as Ki67, the expression of which was studied in tumor tissue obtained from SAKK trials. The group was able to publish the second trial on this topic in 2019 in *Scientific Reports* (Varga et al., 2019). The Pathology section continues to participate on a scientific level in the implementation of the translational research project associated with the **SAKK 75/08** trial (cetuximab in neoadjuvant therapy of esophageal cancer), in which molecular signatures are being characterized using complex and comprehensive molecular genetic methods in patients' tumor tissue and correlated with the response to subsequent preoperative (neoadjuvant) therapy.

Section Radio-Oncology

President: Prof. Dr. med. Frank Zimmermann,
University Hospital Basel

Mixed Recruitment into Active Trials Evaluating Radiation Oncology Aspects

The Radio-Oncology section members were active in the field of solid organs such as head and neck cancer, esophageal carcinoma, breast cancer, and seminoma, with a focus on multimodal treatments.

Whereas the recruitment for node-positive breast cancer (SAKK 23/16 TAXIS) in 2019 fulfilled all expectations and compensated for the slow accrual in 2018, the randomized trials in head and neck cancer (SAKK 10/16-EORTC 1420 'Best Of': comparing surgery with radiation therapy in early stage cancer), in esophageal cancer (PRODIGE 32 – ESOSTRATE 1 – FFCD 1401: sequence of combined radio-chemotherapy and surgery only in a subgroup of patients), and in prostate carcinoma (SAKK 08/15 PROMET: radiation therapy for recurrent prostate cancer, randomizing metformin) needed adaptations in relevant parts of the inclusion criteria but successfully invited further international trial centers. The successor trial of SAKK 01/10 in stage II seminoma was opened in 2019 and started immediately with a positive accrual.

The radiation quality assurance program has proved its worth and was conducted successfully in more than 100 patients in the TAXIS trial. The feedback from the centers was positive, and the program is now a routine program in all SAKK trials using radiation therapy.

Dr. Peter Durrer
Head of Quality Assurance
Regulatory Affairs &
Pharmacovigilance

Creation of New Working Group Cellular Therapies

The use of T-cell therapies to treat cancer is advancing rapidly, opening up promising, personalized treatment options for cancer patients. The first products have already reached the market. Major efforts are being made to further investigate the potential of this form of immunotherapy for various hematological and solid tumors. In light of the leading position of the United States and China in the international field, it is necessary for Swiss research institutes to collaborate closely, so that they can establish themselves as a significant international player in the area of T-cell therapy.

In 2019, the Swiss Cancer Research foundation (KFS) organized two workshops to initiate the implementation of a national platform for cellular therapies. The participants came to the conclusion that research, manufacturing, exchange with regulatory authorities, identification of financial mechanisms to support the development of new T-cell therapy technologies, and monitoring of their results need to be coordinated closely within Switzerland. It was agreed that SAKK is the ideal organization to coordinate these activities.

Consequently, the Working Group Cellular Therapies was established at the SAKK semi-annual meeting in November 2019. The participants at the meeting elected Prof. Dr. med Dr. phil. George Coukos (Lausanne University Hospital CHUV, University of Lausanne, and Ludwig Institute for Cancer Research) as president of the new working group. In addition, three vice presidents were elected to support the president, namely, PD Dr. med. Antonia Müller (Zurich University Hospital, USZ), PD Dr. med. Heinz Läubli, MD PhD (University Hospital Basel, USB), and Prof. Dr. med. Dr. phil. Sacha Zeerleder (University Hospital of Bern).

The Working Group Cellular Therapies focuses on academic research on innovative cellular therapies and on collaborative research with pharmaceutical companies rather than on initiatives aiming to compete with authorized products. Our ultimate goal is to move cell-based technologies rapidly forward to improve cancer care for all our patients.

SAKK wishes Prof. George Coukos and all the researchers involved in the working group constructive discussions and success in setting up this network for cellular therapies. We are convinced that the establishment of this national platform will be of great benefit for cancer patients in Switzerland.

Marie Stöpfer
Project Manager /
Fundraiser

SAKK Patient Advisory Board

SAKK set up the Patient Advisory Board in November 2015 with the aim of gaining a better understanding of the experiences and needs of cancer patients and their families and using this information to inform its research projects. We attach great importance to learning about the experience of patients and their families as a way of achieving improved long-term cancer treatments.

2019 was an eventful year. The Patient Advisory Board received further training in clinical oncological trials and communication with trial patients and was involved in the development of trials from the patients' perspective. In 2019 the Patient Advisory Board supported the development of patient information for six new trials and made valuable suggestions for improvements. The Patient Advisory Board also established that there is potential for improving the templates provided by Swissethics. The suggestions for improving the templates were submitted to Swissethics in early 2019 and were received gratefully by that body.

The Patient Advisory Board implemented a large number of projects for patients in 2019. These include the SAKK Patient Forum, a public event that was held by the Patient Advisory Board during the SAKK semi-annual meeting. The purpose of the Patient Forum is to inform patients, their families, and interested parties about recent developments in oncology. In 2019 the Patient Advisory Board organized two events, each with around 50 participants. The first took place in June. A number of established researchers talked about the current status of research into sarcomas and gastrointestinal stromal tumors (GIST). This is one of the rarest of all cancers. "Sarcomas account for just one percent or so of all cancers in humans," explained Dr. Sander Botter, a member of the SAKK Patient Advisory Board since 2017, "so both people affected and physicians have a great need for information." The presentations covered various aspects, such as new therapies, histology and molecular genetics, surgery, and immunotherapies. The second event, held in November, focused on "Diagnosis of colorectal cancer: Recent research findings for patients." Renowned oncologists and surgeons spoke on a range of topics, including medications and new approaches to the treatment of colorectal cancer, the role of surgery, and risk factors.

The growing number of requests from external partners (including the federal government, research institutes, and healthcare-related organizations) for advice from the SAKK Patient Advisory Board on a wide variety of questions testifies to the important and sustainable work being done by this body. One example was the participation of a member of the SAKK Patient Advisory Board in a workshop to evaluate the Federal Act on Research Involving Human Beings.

Thanks to the valuable support provided by the Rising Tide Foundation for Clinical Cancer Care, the Patient Advisory Board is planning for the coming years new projects as well as further development of existing projects. The Patient Advisory Board would like to make the results of SAKK trials available to participating patients and the general public in easily understood language. SAKK would also like to involve the members of the Patient Advisory Board more intensively in the development of its trials so that the design of these trials, and with it the treatment provided for patients, is better adapted to the needs of these individuals. This is the only way for SAKK to be able to offer patient-oriented trials that represent real added value for people at a difficult time in their lives.

Dr. Jessica Schulz
Clinical Project Manager

Real World Data Project

The Swiss Personalized Health Network (SPHN) was established in 2016 to promote the development of personalized medicine and health in Switzerland. SPHN creates the conditions needed for exchange of health-related data. Swiss Personalized Oncology (SPO), an SPHN Driver Project, aims to achieve harmonization in oncology in order to make data accessible and exchangeable for oncology projects. SPHN is initially concentrating on the five university hospitals in Switzerland and in the longer term would like to expand the concept to the whole country.

SAKK received a larger number of project proposals for oncology registries and data projects between 2016 and 2019. SAKK is seeking to establish the necessary infrastructure so that all 20 SAKK members and their networks can be involved in data projects, thus enabling them to be carried out nationwide and in collaboration with international partners. The concept of a Real World Data (RWD) platform emerged in 2019. The aim of this platform is to make it possible for all members to provide data from everyday clinical practice. At the same time, all researchers will be able to submit project proposals for using data from all over Switzerland to answer research questions. To this end, SAKK will work closely with SPHN/SPO to harmonize Swiss-wide data collection processes, establish technical capacities for all hospitals, and develop guidelines to ensure fair access to the data. The primary goal of this and other collaborative efforts is to nationalize the basic concept, avoid duplication, and bundle expertise. One essential feature here, for example, is a national, harmonized general consent to the transfer and use of health data. SAKK is also liaising closely with National Institute for Cancer Epidemiology and Registration (NICER), which focuses on epidemiological data while SAKK takes a clinical approach.

The RWD platform should make it possible for researchers to network existing oncological registries with this platform and to establish new, high-quality registries that will be managed by SAKK on a long-term basis and in this way also create added value in the future. The data will always be available to the primary project applicant and for future projects. Networking data from the everyday clinical setting will also generate a tremendous learning effect in oncology, since it will be possible to correlate uses, combinations, and effect of cancer therapies with, for example, gender, age, or genetic mutations. This learning effect will not only have a positive impact on oncology research and Switzerland as a research base but will also benefit physicians working in the clinical setting, the healthcare system, and stakeholders (e.g., Federal Office of Public Health, health insurers, and pharmaceutical companies), and it will therefore have a direct impact on patients. This will be an important step towards personalized medicine, a topic that is the focus of international attention and is capable in particular of generating major added value for patients in oncology.

The RWD platform will also enable evidence to be provided for the evaluation of KVV71 cases (off-label use) and to support authorization procedures. RWD is available to all parties at fair and legally sound conditions in order to generate an overall benefit for society through the analysis of data (Figure 1).

SAKK will provide the data collection infrastructure and the expertise for data analysis in 2020. All SAKK members are invited to participate, so that progress can be achieved nationwide and Switzerland can remain internationally competitive. The first RWD project, the Alpine Tumor Immunology Registry (Alpine TIR) proposed by PD Dr. med. Ulf Petrausch, seeks to document and analyze the development and use of immunotherapies in Switzerland. Further projects are scheduled to begin during 2020.

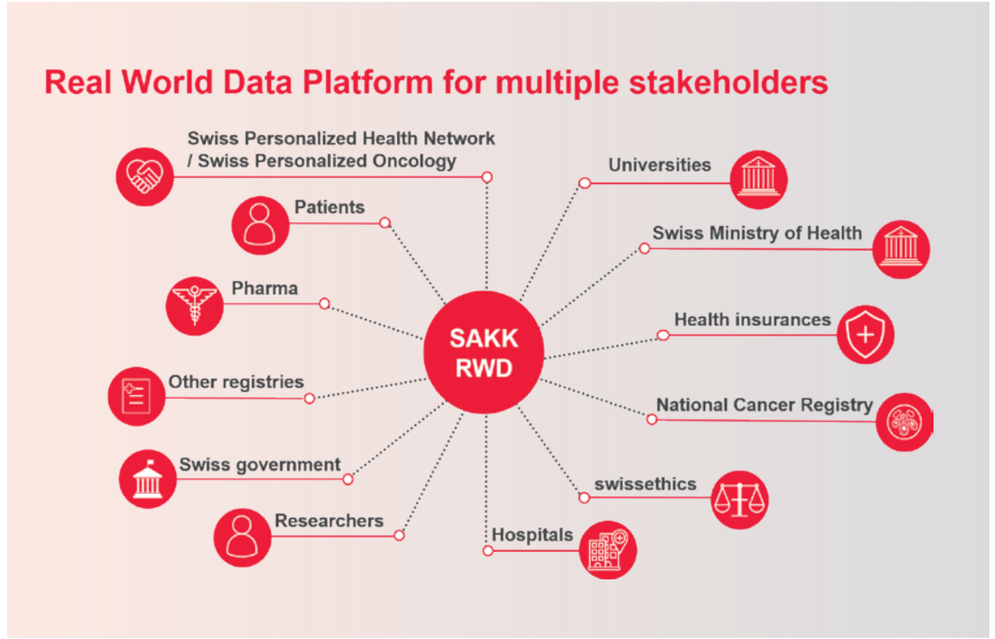


Fig. 1: Real World Data Platform: Bringing progress to cancer care in collaboration with all partners through collection and analysis of healthcare data in clinical practice.

Mark Jensen
Head of Services

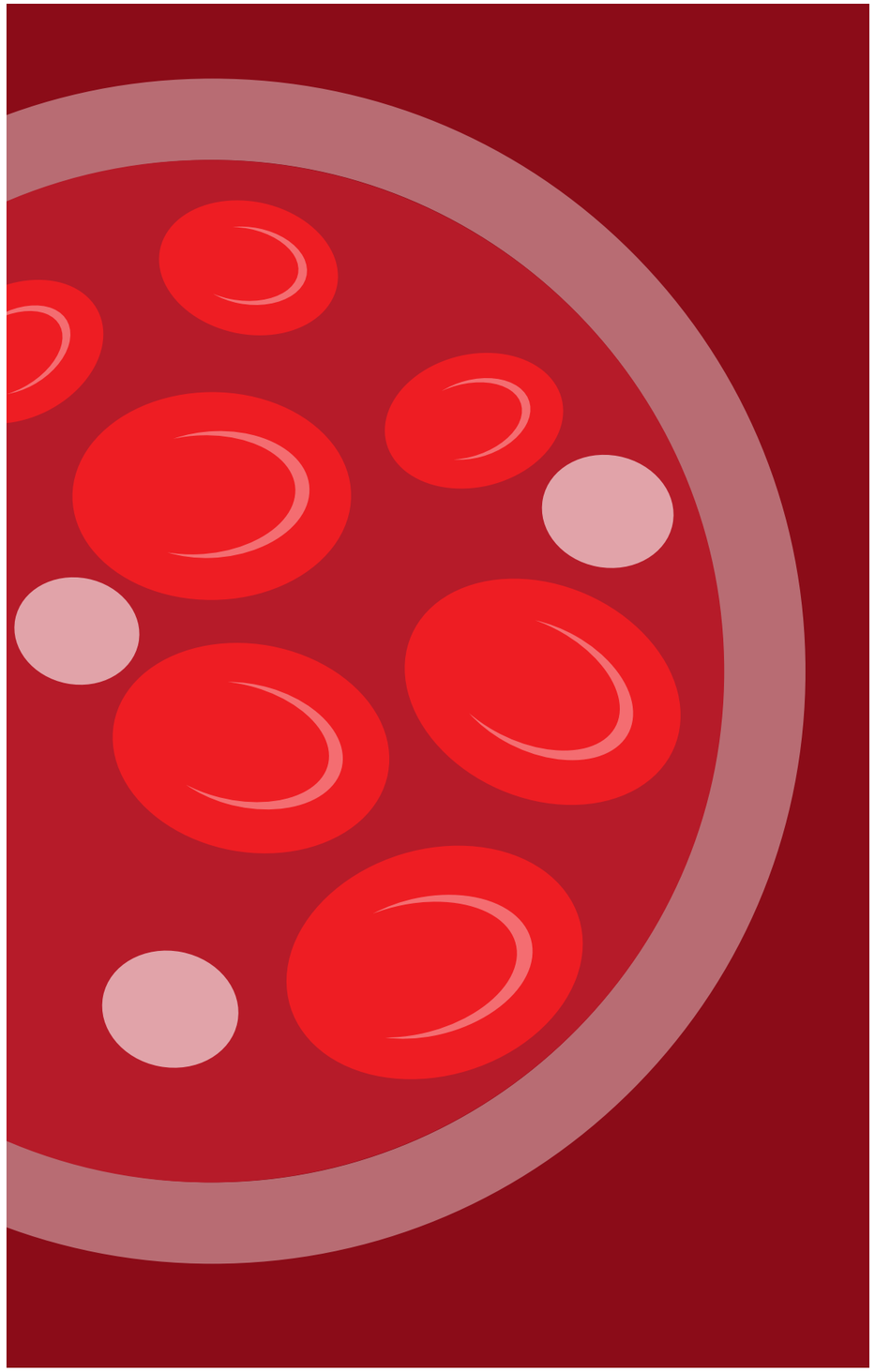
Digitalization at SAKK

Electronic Trial Master File (TMF) in M-Files
SAKK has become a large organization, and it is important for all employees to be able to access relevant documents rapidly. For this reason, we introduced the electronic Trial Master File (eTMF) on July 1, 2019 for the archiving, processing, and management of trial documentation. M-Files, the document management system used for this purpose, complies with all the legal and regulatory requirements (ICH GCP E6(R2) and 21 CFR Part 11). Changes to the documents are clearly recorded (audit trail), and access rights to documents are role-based. Thanks to precisely defined workflows in M-Files, certain documents need to pass through all the necessary steps, such as review, reconciliation, and signature, before they can be finalized. A major advantage of this system is the electronic signature option. External investigators can also directly access the system and sign documents, saving us a lot of time and administrative effort. In addition, the version control in M-Files ensures that everyone accesses the current version of documents and does not use old versions by mistake.

Data Warehouse, Report Server, and CUBE for Reporting
In 2019 we expanded the Data Warehouse, adding the Report Server for standard reports specifically for Quality Affairs (QA) and Regulatory Affairs (RA). We also refined CUBE, a database based on the Data Warehouse that is used for ad hoc Excel reports. Additional data on change applications, sponsors' representatives, and translational subprojects for all trials were added to Data Warehouse, Report Server, and CUBE. SAKK derives additional efficiency and data quality from the automation of reporting.

Following the introduction of the new system, we have started to implement a systematic change process. This will enable us to ensure that the reports comply with requirements, are of high quality, and are produced on time.

An Accounting Highlight in 2019: Introduction of the Electronic Creditor Process
In the past there was a great deal of manual work associated with processing invoices sent to us. The introduction of the electronic creditor process, which was implemented as a workflow in our ERP system (ABACUS), allows invoices to be processed through SAKK considerably faster and, above all, more efficiently than before. Invoices are automatically recorded by the system as soon as they are scanned in and are delivered to the responsible person. This means that the processing status can be seen at all times. Furthermore, this ensures that invoices are paid punctually, as delegation rules apply if the person responsible is absent. The introduction of the electronic creditor process has led to a tangible increase in quality, reliability, and security.



Christine Biaggi Rudolf
Chief Operations Officer

Dr. Peter Durrer
Head of Quality Assurance
Regulatory Affairs &
Pharmacovigilance

Dr. Stefanie Hayoz
Head of Statistics

Trial and Patient Figures Again Very Good
In 2019 we again saw a pleasing increase in trial activities, with more patients enrolled in a greater number of trials overall. We recruited a total of 1,335 patients into the 62 open trials conducted by SAKK (including retrospective trials and registries), 1,153 of them from the Swiss member hospitals. This represented a slight decrease in patient numbers compared with 2018 (-14 %), however.

It is therefore all the more positive that the number of patients recruited into prospective clinical trials grew substantially, from 948 in 2018 to 1,211 in 2019 – i.e., an increase of 28 %. The aim of further increasing the number of patients in clinical trials was thus clearly achieved in 2019.

Regulatory Approval of Trial Activities
The number of trials submitted to the authorities and approved in 2019 was comparable to the previous year's figure.

Collaboration with Swissethics, the ethics committees, and Swissmedic was further improved and resulted in shorter processing times. Approval of trial networks was challenging at times in 2019 and resulted in additional questions to the ethics committees, which delayed the recognition of these networks. Several meetings were held with the ethics committees to exchange views, and this had a positive effect on collaboration and reciprocal understanding.

More Evaluation of Safety Signals by the SAKK Safety Office
The SAKK Safety Office again noted the distinct increase in SAKK trial activities last year. The number of Serious Adverse Events (SAEs) requiring evaluation rose by 38 %, although there was only a slight increase in the number of annual safety reports written. Continuous process improvements enabled the SAKK Safety Office to handle the increase and perform assessments in compliance with the regulatory requirements. The process will be further automated over the coming year in order to further simplify administration.

Quality Assurance Can Identify Systematic and Cross-Trial Deviations More Rapidly
The introduction of electronic detection of deviations in secuTrial© established a tool that permits the quality assurance department and people working on trials to evaluate deviation-related data promptly and systematically. This will make it possible in the future to identify systematic deviations or patterns at an even earlier stage and to take corrective or preventive actions.

Trial Results and Publications

Last year, 36 articles with SAKK participation appeared in various scientific journals. The full list can be found on page 56–60.

SAKK was well represented at the major oncology congresses as well as at more local events with 11 posters and 10 oral presentations, including an oral presentation at the European Society for Medical Oncology (ESMO) Congress 2019, one at ESMO Breast Cancer 2019, and one at the 2019 Genitourinary Cancers Symposium organized by the American Society of Clinical Oncology (ASCO GU). A full list of all presentations can be found on page 61–62.

As part of our statistical advisory work, we were also able to assist with approximately 19 smaller and larger non-SAKK projects and contribute to presentations and manuscripts.

The statistics team produced 17 clinical trial reports, including five final reports for the authorities.

Balance sheet

As of December 31 (in CHF)	**2019**		**2018**	
Assets				
Cash and cash equivalents	10’622’455.50		10’716’389.68	
Accounts receivable	4’693’599.01		1’425’178.46	
Other accounts receivable	66’247.32		19’402.27	
Prepaid expenses and deferred income	1’247’586.06		2’654’174.80	
Total current assets	**16’629’887.89**	61.8 %	**14’815’145.21**	62.1 %
Financial assets	10’301’022.00		9’032’316.00	
Total fixed assets	**10’301’022.00**	38.2 %	**9’032’316.00**	37.9 %
Total assets	**26’930’909.89**	100.0 %	**23’847’461.21**	100.0 %
Liabilities				
Accounts payable	3’491’014.01		3’015’930.27	
Other accounts payable	222’506.24		172’490.21	
Deferred income and accrued expenses	7’299’232.92		5’816’522.91	
Total short-term liabilities	**11’012’753.17**	40.9 %	**9’004’943.39**	37.8 %
Provisions for liability claims	608’155.88		608’155.88	
Other Provisions	-		-	
Total long-term liabilities	**608’155.88**	2.3 %	**608’155.88**	2.6 %
«Education Grant» fund	30’000.00		30’000.00	
«Special purpose» fund	217’932.38		167’932.38	
«Hubacher» fund	11’040’399.82		9’804’409.62	
Total special purpose fund capital	11’288’332.20	41.9 %	10’002’342.00	41.9 %
Organizational capital				
Free capital as at 1 January	4’232’019.94		3’964’681.14	
Group result	-210’351.30		267’338.80	
Free capital as at 31 December	4’021’668.64		4’232’019.94	
Total organizational capital	**4’021’668.64**	14.9 %	**4’232’019.94**	17.7 %
Total liabilities	**26’930’909.89**	100.0 %	**23’847’461.21**	100.0 %

Statement of operations

January 1 to December 31 (in CHF)	**2019**		**2018**	
Operating income				
Research contributions SERI[1]	5’836’218.00		5’628’614.00	
Research contributions CLS[2]	376’050.00		441’850.00	
Research contributions CRS[3]	2’340’350.00		1’394’850.00	
Research contributions SSKK[4]	100’000.00		100’000.00	
Research contributions, third parties	1’891’351.79		644’459.85	
Research contributions, Swiss health insurers	2’245’295.20		2’365’435.25	
Income from industry partnerships	8’426’981.77		8’570’296.01	
Income from foreign study groups	334’414.88		465’146.25	
Income from Cancer Bulletin	207’148.72		224’987.52	
Income from Patient Advisory Board	20’000.00		35’275.00	
Donations, bequests, legacies	349’574.26		61’860.56	
Miscellaneous income	974’359.35		617’248.88	
Losses on receivables	-44’119.00		105’000.00	
Total operating income	**23’057’624.97**	100.0 %	**20’655’023.32**	100.0 %
Operating costs				
Miscellaneous study-related expenses	-1’883’320.94		-1’583’334.90	
Research contributions IBCSG, ETOP[5]	-420’756.91		-176’666.00	
Research contributions, centers	-7’433’394.80		-6’787’186.71	
Travel, hospitality expenses	-1’061’276.85		-462’527.60	
Other operating expenses	-209’113.49		-142’497.71	
Total operating expenses	**-11’007’862.99**	-47.7 %	**-9’152’212.92**	-44.3 %
Interim result 1	**12’049’761.98**	52.3 %	**11’502’810.40**	55.7 %
Coordination expenses				
Personnel expenses	-9’636’039.46		-9’186’333.44	
Other coordination expenses	-1’929’614.22		-2’063’179.56	
Total coordination expenses	**-11’565’653.68**	-50.2 %	**-11’249’513.00**	-54.5 %
Interim result 2	**484’108.30**	2.1 %	**253’297.40**	1.2 %
Financial result				
Financial income	32’968.88		43’040.15	
Financial expenses	-77’428.48		-45’205.20	
Total financial result	**-44’459.60**	-0.2 %	**-2’165.05**	0.0 %
Interim result 3	**439’648.70**	1.9 %	**251’132.35**	1.2 %
Out-of-period result				
Out-of period income	-		16’279.75	
Out-of period expenses	-650’000.00		-73.30	
Total out-of-period result relating to a different accounting period	-650’000.00	-2.8 %	16’206.45	0.1 %
Annual result	**-210’351.30**	-0.9 %	**267’338.80**	1.3 %

1 State Secretariat for Education, Research and Innovation 2 Cancer league Switzerland 3 Cancer Research Switzerland
4 Swiss Foundation for Clinical Cancer Research 5 International Breast Cancer Study Group, European Thoracic Oncology Platform

Notes to the 2019 annual financial statements

As of December 31	2019	2018
Information compliant with Art. 957–962 SCO		
Number of personnel		
Bandwidth of full-time equivalents (average for year)	>50 bis 250	>50 bis 250
Valuation of assets at market value		
Financial investments at market value on 31.12	10'301'022.00 CHF	9'032'316.00 CHF
Auditors' fee		
Fee for auditing services	9'531.45 CHF	8'616.00 CHF
Fee for other services	0.00 CHF	0.00 CHF
Remainder of liabilities from purchase contract-type leasing transactions and other leasing liabilities not maturing or called within 12 months after the balance sheet date.		
Fixed rental contract (offices) up to 31.5.2026	81'825 CHF	94'577 CHF
Fixed rental contract (offices) up to 30.4.2026	1'715'991 CHF	1'986'937 CHF
Fixed rental contract (offices) up to 30.8.2027	664'394 CHF	751'054 CHF
Total	2'462'210 CHF	2'832'568 CHF
Notes on extraordinary, non-recurring or out-of-period items in the income statement		
Out-of-period expenses	-650'000 CHF	-73 CHF
Out-of-period income	0 CHF	16'280 CHF
Total	-650'000 CHF	16'206 CHF

These annual financial statements have been prepared in accordance with the requirements of Swiss law, in particular the articles on commercial accounting and financial reporting in the Code of Obligations (Art. 957 to 962).

BDO

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BDO Ltd
Hodlerstrasse 5
3001 Berne

REPORT OF THE STATUTORY AUDITOR
To the General Assembly of the Swiss Group for Clinical Cancer Research, Berne

Report of the Statutory Auditor on the Financial Statements

As statutory auditor, we have audited the accompanying financial statements of the Swiss Group for Clinical Cancer Research, which comprise the balance sheet as per 31st December 2019, the income statement, the cash flow statement, the statements of changes in equity/funds and notes for the year then ended.

Board's Responsibility

The Board is responsible for the preparation of these financial statements in accordance with the requirements of Swiss law and the company's articles of incorporation. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation of financial statements that are free from material misstatement, whether due to fraud or error. The Board is further responsible for selecting and applying appropriate accounting policies and making accounting estimates that are reasonable in the circumstances.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with Swiss law and Swiss Auditing Standards. Those standards require that we plan and perform the audit to obtain reasonable assurance whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers the internal control system relevant to the entity's preparation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control system. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made, as well as evaluating the overall presentation of the financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements for the year ended 31st December 2019 comply with Swiss law and the company's articles of incorporation.

Report on Other Legal Requirements

We confirm that we meet the legal requirements on licensing according to the Auditor Oversight Act (AOA) and independence (article 728 Code of Obligations (CO)) and that there are no circumstances incompatible with our independence.

In accordance with article 728a para. 1 item 3 CO and Swiss Auditing Standard 890, we confirm that an internal control system exists, which has been designed for the preparation of financial statements according to the instructions of the Board.

Berne, 3 April 2020

BDO Ltd

Matthias Hildebrandt

Auditor in Charge
Licensed Audit Expert

i. V. Laurence Gilliéron

Advisory Board

General Assembly

Aargau	Baden	Basel	Bern	Biel
Fribourg	Genève	Graubünden	Hirslanden	Solothurn
St. Gallen	Thun	Thurgau	Ticino	Valais
Vaud	Winterthur	Zentralschweiz	Zürich Triemli	Zürich USZ
Budapest	Strasbourg	Freiburg i. B.	Feldkirch	

Chairman

SAKK Board

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Gastrointestinal Cancer
PD Dr. med. Dr. phil. Andreas Wicki

Leukemia
Prof. Dr. med. Thomas Pabst

Lung Cancer
Prof. Dr. med. Martin Früh

Lymphoma
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Prof. Dr. med. Markus Jörger

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Immuno-Oncology
Prof. Dr. med. phil. George Coukos

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Sarcoma
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Supportive Care & Palliative Cancer Care
Prof. Dr. rer. med. Manuela Eicher

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Network for Cancer Predisposition Testing and Counseling
PD Dr. med. Sheila Unger

Network for Outcomes Research
Dr. med. Konstantin Dedes

Pathology
Prof. Dr. Rupert Langer

Radio-Oncology
Prof. Dr. Frank Zimmermann

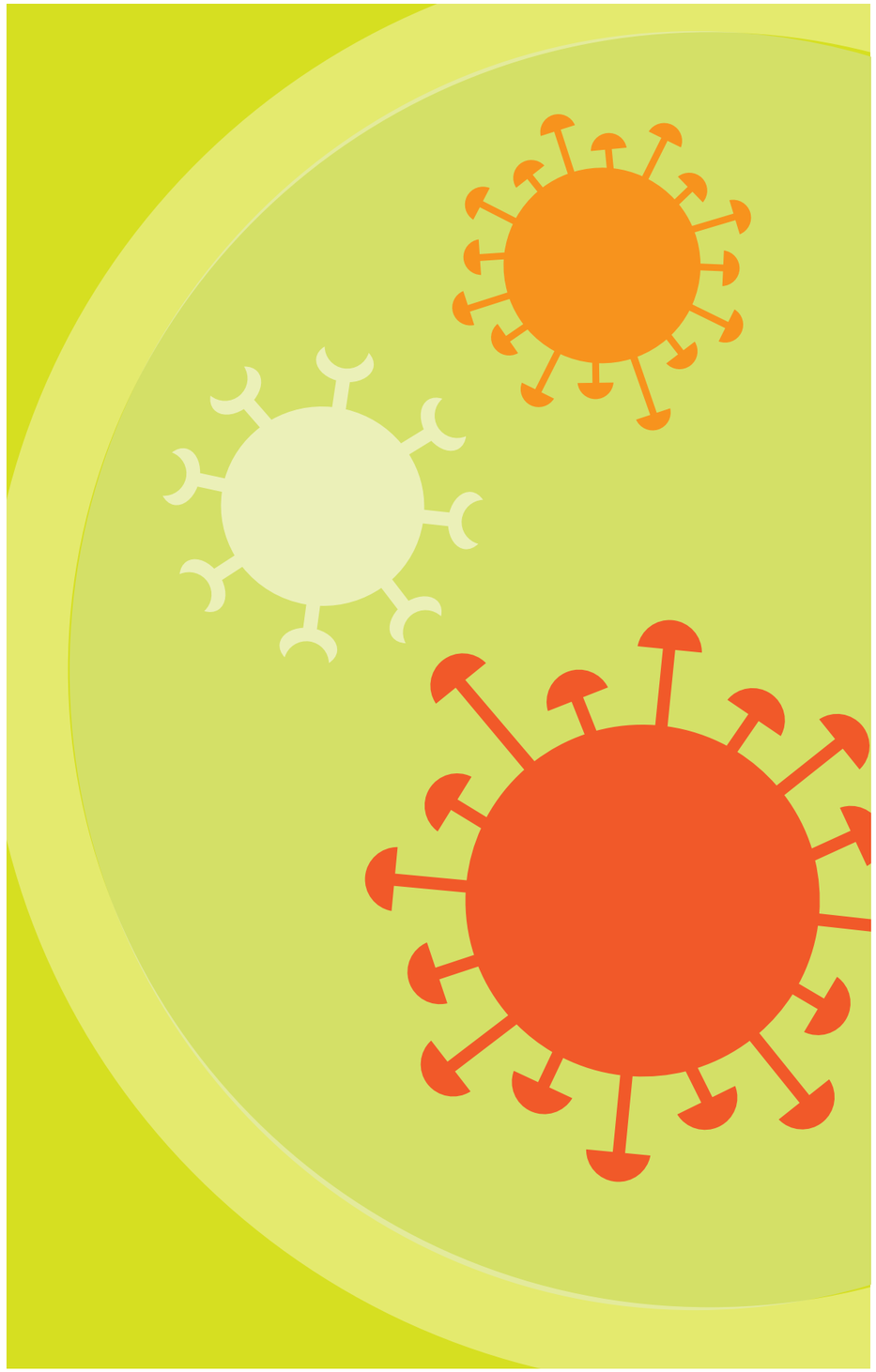
Surgery
Prof. Dr. med. Christoph Kettelhack

SAKK Coordinating Center

CEO

Executive Board

- Clinical Trial Management
- Fundraising & Communication
- QA & Regulatory Affairs & Safety Office
- Services (IT/Accounting)



SAKK Board

Prof. Dr. med.
Roger von Moos
Cantonal Hospital Graubünden
(President)

Prof. Dr. med.
Miklos Pless
Cantonal Hospital Winterthur
(Vice President)

Prof. Dr. med.
Gabriela Baerlocher
University Hospital Bern

Prof. Dr. med.
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PD Dr. med.
Richard Cathomas
Cantonal Hospital Graubünden

Prof. Dr. med.
Christoph Driessen
Cantonal Hospital St. Gallen

Prof. Dr. med.
Olivier Michielin
Centre Hospitalier Universitaire
Vaudois CHUV

Prof. Dr. med.
Ellen C. Obermann
Luzerner Kantonsspital

Prof. Dr. med.
Bernhard C. Pestalozzi
University Hospital Zurich

PD Dr. med. Dr. phil.
Sacha Rothschild
University of Basel

Dr. med.
Thomas Zilli
Hôpitaux Universitaire
de Genève HUG

Prof. Dr. med.
Emanuele Zucca
Oncology Institute of Southern
Switzerland (IOSI)

The Swiss Group for Clinical Cancer Research SAKK would like to express gratitude for the generous support received.

Contributions from the Public Sector and Third Parties:
- State Secretariat for Education, Research and Innovation (SERI)
- Swiss Cancer Research Foundation
- Swiss Cancer League
- Administrative commission for the Fund LOA IV/1
- Basel Cancer League
- Bern Cancer League
- Claudia von Schilling Foundation for Breast Cancer Research
- Fond'Action contre le Cancer
- Fondation Joseph et Lina Spicher
- Fondation pour la Recherche et le Traitement Médical
- Gateway for Cancer Research
- Hedy Glor-Meyer Stiftung
- Pink Ribbon
- Private donors
- Promedica
- Rising Tide Foundation for Clinical Cancer Research
- Swiss Clinical Cancer Research Foundation (SSKK)
- Stiftung zur Krebsbekämpfung
- Werner and Hedy Berger-Janser Foundation (Werner und Hedy Berger-Janser Stiftung zur Erforschung der Krebskrankheiten)

SAKK Industry Pool 2019
Sincere Thanks to the Following Pharmaceutical Companies for Their Support:
- AbbVie AG
- Amgen Switzerland AG
- Astellas Pharma AG
- AstraZeneca A0G
- Bayer (Schweiz) AG
- Boehringer Ingelheim (Schweiz) GmbH
- Bristol-Myers Squibb SA
- Celgene GmbH
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- Eli Lilly (Suisse) SA
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- Gilead Sciences Switzerland Sàrl
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- Roche Pharma (Schweiz) AG
- Sandoz Pharmaceuticals AG
- Servier (Suisse) S.A.
- Takeda Pharma AG
- TESARO Bio GmbH
- Teva Pharma AG
- Vifor AG

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IBAN: CH68 0900 0000 6029 5422 0
PostFinance AG, Mingerstrasse 20, 3030 Bern
BIC/SWIFT: POFICHBEXXX
Clearing no. (BLZ): 9000

Conducted Trials 2019

Trials activated in 2019

Trial name	Trial title	Coordinating investigator	Activation
Breast Cancers			
IBCSG 59-19 POLAR	A phase III open-label, multicenter, randomized trial of adjuvant palbociclib in combination with endocrine therapy versus endocrine therapy alone for patients with hormone receptor positive / HER2-negative resected isolated locoregional recurrence of breast cancer.	Stefan Paul Aebi	27.08.2019
SAKK 21/18	Ribociclib-endocrine therapy combination versus chemo-therapy as 1st line treatment in patients with visceral metastatic breast cancer. A multicenter, randomized phase III trial.	Thomas Ruhstaller	25.06.2019
SAKK 95/17	A 24 weeks activity program in patients with early breast cancer receiving aromatase inhibitor therapy. A multicenter randomized phase III trial.	Nicolette Hoefnagels	18.03.2019
Gynecological Cancers			
ENGOT-ov50_ INNOVATE-3	Pivotal, randomized, open-label study of Tumor Treating Fields (TTFields, 200kHz) concomitant with weekly paclitaxel for the treatment of platinum-resistant ovarian cancer (PROC).	Eleftherios Pierre Samartzis	03.06.2019
Leukemias			
HOVON 150	A phase 3, multicenter, double-blind, randomized, placebo-controlled study of ivosidenib or enasidenib in combination with induction therapy and consolidation therapy followed by maintenance therapy in patients with newly diagnosed acute myeloid leukemia or myelodys-plastic syndrome with excess blasts-2, with an IDH1 or IDH2 mutation, eligible for intensive chemotherapy.	Markus G. Manz	05.12.2019
SAKK 34/17	Prospective, open-label, multicenter, phase-II trial of ibrutinib induction followed by ibrutinib plus venetoclax consolidation in patients with relapsed/refractory chronic lymphocytic leukemia.	Davide Rossi	21.02.2019
Lung Cancers			
EORTC HALT	Targeted therapy beyond progression with or without dose-intensified radiotHerapy in oligo-progressive disease (OPD) in oncogene Addicted Lung Tumours (HALT). An international, randomized, multi-center, phase II/III study.	Matthias Guckenberger	13.06.2019
ETOP BEAT-meso	A multicentre randomised phase III trial comparing atezo-lizumab plus bevacizumab and standard chemotherapy versus bevacizumab and standard chemotherapy as first-line treatment in advanced malignant pleural mesothelioma.	Amina Scherz	06.06.2019
ETOP CHESS	A multicentre single arm phase II trial assessing the efficacy of radical immunotherapy and chemotherapy, stereotactic radiotherapy and surgery in patients with synchronous oligo-metastatic NSCLC.	Rolf A. Stahel	10.10.2019
SAKK 19/18	Fibroblast growth factor receptor (FGFR) inhibitor rogara-tinib in patients with advanced pretreated squamous-cell non-small cell lung cancer (SQCLC) overexpressing FGFR mRNA. A multicenter, single-arm phase II trial.	Alfredo Addeo	29.05.2019
Lymphomas			
EMCL-Registry	The Registry of the European Mantle Cell Lymphoma study group.	Martin Fehr	20.12.2019
IELSG-45	Randomized phase II trial on fitness- and comorbidity-tailored treatment in elderly patients with newly diagnosed Primary CNS Lymphoma.	Benjamin Kasenda	27.05.2019
New treatments			
SAKK 66/18	Copanlisib in combination with venetoclax in patients with relapsed or refractory B-cell non-Hodgkin lymphoma. A multicenter phase Ib trial with two expansion cohorts.	Anastasios Stathis	13.09.2019
Sarcomas			
GISG 11, PazoQoL	PazoQoL Quality of life in patients with non-adipocyte soft tissue sarcoma under palliative chemotherapy or pazopanib – a randomized, controlled trial.	Silvia Hofer	04.06.2019
Urogenital Cancers			
PEACE-4	A Phase III trial of acetylsalicylic acid and atorvastatin in patients with castrate-resistant prostate cancer.	Aurelius Omlin	16.04.2019
SAKK 01/18	Reduced intensity radiochemotherapy for Stage IIA/B Seminoma.	Alexandros Papachristofilou	11.07.2019
SAKK 09/18	Extended pelvic lymph node dissection vs. no pelvic lymph node dissection at radical prostatectomy for intermediate- and high-risk prostate cancer: An international, multicenter, randomized phase III trial.	Cyrill Rentsch	11.07.2019

Trials open for accrual in 2019

Trial name	Trial title	Coordinating investigator	Activation
Breast Cancers			
IBCSG 48-14 POSITIVE	A study evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy (POSITIVE).	Olivia Pagani	02.12.2014
IBCSG 50-14 OLYMPIA	A randomised, double-blind, parallel group, placebo-controlled multi-centre Phase III study to assess the efficacy and safety of olaparib vs placebo as adjuvant treatment in patients with high risk germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy.	Urban Novak	23.11.2015
IBCSG 55-17 TOUCH	Phase II open-label, multicenter, randomized trial of neoadjuvant palbociclib in combination with hormonal therapy and HER2 blockade versus paclitaxel in combina-tion with HER2 blockade for elderly patients with hormone receptor positive/HER2 positive early breast cancer.	Patrik Weder	30.10.2018
IBCSG 59-19 POLAR	A phase III open-label, multicenter, randomized trial of adjuvant palbociclib in combination with endocrine therapy versus endocrine therapy alone for patients with hormone receptor positive / HER2-negative resected isolated locoregional recurrence of breast cancer.	Stefan Paul Aebi	27.08.2019

Trial name	Trial title	Coordinating investigator	Activation
SAKK 21/18	Ribociclib-endocrine therapy combination versus chemo-therapy as 1st line treatment in patients with visceral metastatic breast cancer. A multicenter, randomized phase III trial.	Thomas Ruhstaller	25.06.2019
SAKK 23/16	Tailored AXIllary Surgery with or without axillary lymph node dissection followed by radiotherapy in patients with clinically node-positive breast cancer (TAXIS). A multicenter randomized open labeled phase III trial.	Walter Weber	31.07.2018
SAKK 24/14	Anti-EGFR-immunoliposomes loaded with doxorubicin in patients with advanced triple negative EGFR positive breast cancer - A multicenter single arm phase II trial.	Ralph Winterhalder	20.10.2016
SAKK 25/14	Eribulin as 1st line treatment in elderly patients (>= 70 years) with advanced breast cancer: a multicenter phase II trial.	Ursula Hasler-Strub	11.10.2015
SAKK 95/17	A 24 weeks activity program in patients with early breast cancer receiving aromatase inhibitor therapy. A multicenter randomized phase III trial.	Nicolette Hoefnagels	18.03.2019
SAKK 96/12	Prevention of Symptomatic Skeletal Events with Denosumab Administered every 4 Weeks versus every 12 Weeks – A Non-Inferiority Phase III Trial.	A. Müller	16.07.2014
Gastrointestinal Cancers			
PRODIGE 32	Systematic surgery vs. monitoring and salvage surgery in operable oesophageal cancer in complete clinical response after chemotherapy. Strategic multicenter randomized phase II-III trial.	Thomas Ruhstaller	28.03.2017
SAKK 41/13	Adjuvant aspirin treatment in PIK3CA mutated colon cancer patients. A randomized, double-blinded, placebo-controlled, phase III trial.	Ulrich Güller	26.04.2016
SAKK 41/14	Physical activity program in patients with metastatic colorectal cancer who receive palliative first-line chemo-therapy. A multicenter open label randomized controlled trial.	Viviane Hess	29.01.2016
SAKK 41/16	SAKK 41/16 (RECAP trial): Neoadjuvant treatment with Regorafenib and Capecitabine combined with radio-therapy in locally advanced rectal cancer. A Phase Ib trial.	Sara Bastian	27.02.2017
Gynecological Cancers			
ENGOT-en7_ AtTEnd	Phase III double-blind randomized placebo controlled trial of Atezolizumab in combination with Paclitaxel and Carboplatin in women with advanced/recurrent endo-metrial cancer.	Manuela Rabaglio-Poretti	21.12.2018
ENGOT-ov50_ INNOVATE-3	Pivotal, randomized, open-label study of Tumor Treating Fields (TTFields, 200kHz) concomitant with weekly paclitaxel for the treatment of platinum-resistant ovarian cancer (PROC).	Eleftherios Pierre Samartzis	03.06.2019
Head and Neck Cancers			
SAKK 10/16	Phase III study assessing The "best of" radiotherapy compared to the "best of" surgery (trans-oral surgery (TOS) in patients with T1-T2, N0 oropharyngeal carcinoma.	Frank Zimmermann	27.11.2017
Leukemias			
CLL13	A phase 3 multicenter, randomized, prospective, open-label trial of standard chemoimmunotherapy (FCR/BR) versus rituximab plus venetoclax (RVe) versus obinutuzumab (GA101) plus venetoclax (GVe) versus obinutuzumab plus ibrutinib plus venetoclax (GIVe) in fit patients with previously untreated chronic lymphocytic leukemia (CLL) without Del(17p) or TP53 mutation.	Michael Gregor	17.07.2017
GRAALL 2014	Multicenter trial for the treatment of Acute Lymphoblastic Leukemia (ALL) in younger adults (18-59 years) – Compris-ing 3 sub-studies according to lineage (2 sub-substudies) GRAALL-2014/B & QUEST substudy Ph-negative B-lineage ALL GRAALL-2014/T & ATRIALL substudy T-ALL GRAAPH-2014 Ph+ ALL .	Yves Chalandon	03.05.2016
HOVON 103-SEL	A randomized phase II multicenter study with a safety run-in to assess the tolerability and efficacy of the addition of oral selinexor (KPT-330) to standard induction chemo-therapy in AML and high risk myelodysplasia (MDS) (IPSS-R > 4.5) in patients aged >=66 years.	Georg Stüssi	19.06.2017
HOVON 150	A phase 3, multicenter, double-blind, randomized, placebo-controlled study of ivosidenib or enasidenib in combination with induction therapy and consolidation therapy followed by maintenance therapy in patients with newly diagnosed acute myeloid leukemia or myelodys-plastic syndrome with excess blasts-2, with an IDH1 or IDH2 mutation, eligible for intensive chemotherapy.	Markus G. Manz	05.12.2019
SAKK 34/17	Prospective, open-label, multicenter, phase-II trial of ibrutinib induction followed by ibrutinib plus venetoclax consolidation in patients with relapsed/refractory chronic lymphocytic leukemia.	Davide Rossi	21.02.2019
Lung Cancers			
EORTC HALT	Targeted therapy beyond progression with or without dose-intensified radiotHerapy in oligo-progressive disease (OPD) in oncogene Addicted Lung Tumours (HALT). An international, randomized, multi-center, phase II/III study.	Matthias Guckenberger	13.06.2019
EORTC PEARLS	A randomized, phase 3 trial with anti-PD-1 monoclonal antibody pembrolizumab (MK-3475) versus placebo for patients with early stage NSCLC after resection and completion of standard adjuvant therapy (PEARLS).	Alessandra Curioni Fontecedro	08.02.2016
ETOP ALERT	Single arm phase II trial evaluating the activity of Alectinib for the treatment of pretreated RET-rearranged advanced NSCLC.	Christian Britschgi	05.06.2018
ETOP BEAT-meso	A multicentre randomised phase III trial comparing atezoli-zumab plus bevacizumab and standard chemotherapy ver-sus bevacizumab and standard chemotherapy as first-line treatment in advanced malignant pleural mesothelioma.	Amina Scherz	06.06.2019
ETOP BOOSTER	A randomised phase II trial of osimertinib and bevacizumab versus osimertinib alone as second-line treatment in stage IIIb-IVb NSCLC with confirmed EGFRm and T790M.	Martin Früh	15.06.2017
ETOP CHESS	A multicentre single arm phase II trial assessing the efficacy of radical immunotherapy and chemotherapy, stereotactic radiotherapy and surgery in patients with synchronous oligo-metastatic NSCLC.	Rolf A. Stahel	10.10.2019
SAKK 16/14	Anti-PD-L1 antibody MEDI4736 in addition to neoadjuvant chemotherapy in patients with stage IIIA(N2) non-small cell lung cancer (NSCLC). A multicenter single-arm phase II trial.	Sacha Rothschild	11.04.2016
SAKK 19/16	Binimetinib, pemetrexed and cisplatin, followed by main-tenance with binimetinib and pemetrexed, in patients with advanced non-small cell lung cancer with KRAS mutations. A multicenter phase IB trial.	Martin Früh	25.04.2017
SAKK 19/17	First line durvalumab in patients with PD-L1 positive, advanced NSCLC with performance status 2 unsuitable for combination chemotherapy. A multicenter, single-arm phase II trial.	Michael Mark	23.10.2018

Trial name	Trial title	Coordinating investigator	Activation
SAKK 19/18	Fibroblast growth factor receptor (FGFR) inhibitor rogaratinib in patients with advanced pretreated squamous-cell non-small cell lung cancer (SQCLC) overexpressing FGFR mRNA. A multicenter, single-arm phase II trial.	Alfredo Addeo	29.05.2019
Lymphomas			
EMCL-Registry	The Registry of the European Mantle Cell Lymphoma study group.	Martin Fehr	20.12.2019
HD 21	HD21 for advanced stages: Treatment optimization trial in the first-line treatment of advanced stage Hodgkin lymphoma; comparison of 4-6 cycles of escalated BEACOPP with 4-6 cycles of BrECADD.	Alden Moccia	29.03.2017
HOVON 127/ SAKK 37/16	Phase III study comparing R-CODOX-M/R-IVAC versus dose-adjusted EPOCH-R (DA-EPOCH-R) for patients with newly diagnosed high risk Burkitt lymphoma.	Frank Stenner	11.01.2018
IELSG-37	A randomized, open-label, multicentre, two-arm phase III comparative study assessing the role of involved mediastinal radiotherapy after Rituximab containing chemotherapy regimens to patients with newly diagnosed Primary Mediastinal Large B-Cell Lymphoma (PMLBCL).	Emanuele Zucca	15.11.2011
IELSG-43	High-dose chemotherapy and autologous stem cell transplant consolidating conventional chemotherapy in primary CNS lymphoma -randomized phase III trial (Matrix).	Thomas Pabst	12.11.2018
IELSG-45	Randomized phase II trial on fitness- and comorbidity-tailored treatment in elderly patients with newly diagnosed Primary CNS Lymphoma.	Benjamin Kasenda	27.05.2019
SAKK 35/14	Rituximab with or without ibrutinib for untreated patients with advanced follicular lymphoma in need of therapy. A randomized, double-blinded, SAKK and NLG collaborative Phase II trial.	Emanuele Zucca	15.10.2015
SAKK 35/15	A phase I trial of obinutuzumab in combination with venetoclax in previously untreated follicular lymphoma patients.	Anastasios Stathis	23.02.2017
SAKK 36/13	Combination of ibrutinib and Bortezomib followed by ibrutinib maintenance to treat patients with relapsed and refractory mantle cell lymphoma. A multicenter Phase I/II trial.	Urban Novak	11.08.2015
SAKK 39/16	Alternate day dosing of Pomalidomide in patients with refractory Multiple Myeloma. A multicenter, single arm, open label phase II trial.	Thilo Zander	16.08.2018
TRIANGLE	Autologous Transplantation after a Rituximab/Ibrutinib/ Ara-c containing Induction in Generalized Mantle Cell Lymphoma – a randomized European MCL Network Trial.	Ulrich Mey	29.01.2018
New treatments			
SAKK 11/16	Personalized and cell-based antitumor immunization MVX-ONCO-1 in advanced head and neck squamous cell carcinoma. A single arm, open label, multicenter phase II trial.	Olivier Michielin	27.06.2017
SAKK 65/16	TLD-1, a novel liposomal doxorubicin, in patients with advanced solid tumors. A multicenter open-label single-arm phase I trial.	Dagmar Hess	26.10.2018
SAKK 66/18	Copanlisib in combination with venetoclax in patients with relapsed or refractory B-cell non-Hodgkin lymphoma. A multicenter phase Ib trial with two expansion cohorts.	Anastasios Stathis	13.09.2019
SAKK 67/15	An open-label Phase 1/2a study of BAL101553 administered as intravenous 48-hour infusions in adult patients with advanced solid tumors or recurrent glioblastoma.	Markus Jörger	19.08.2016

Trial name	Trial title	Coordinating investigator	Activation
SAKK 68/17	A phase I study of LY3200882 in patients with solid tumors (oral TGFß inhibitor).		13.09.2018
SAKK 69/17	Open-label, FIH dose-escalation study to evaluate the safety, tolerability, PK, PD, MTD or optimum biologic dose of the ATR inhibitor BAY 1895344 in patients with advanced solid tumors and lymphomas.	Markus Jörger	25.05.2018
Sarcomas			
EURO EWING 2012	International Randomised Controlled Trial for the Treatment of Newly Diagnosed Ewing's Sarcoma Family of Tumours Euro Ewing 2012.	Attila Kollàr	31.08.2018
GISG 11, PazoQoL	PazoQoL Quality of life in patients with non-adipocyte soft tissue sarcoma under palliative chemotherapy or pazopanib — a randomized, controlled trial.	Silvia Hofer	04.06.2019
SAKK 57/16	NAPAGE: NAb-PAclitaxel and GEmcitabine in advanced soft tissue sarcoma. A multicenter open-label single arm phase Ib/IIa trial.	Antonia Digklia	01.10.2018
Urogenital Cancers			
PEACE-4	A Phase III trial of acetylsalicylic acid and atorvastatin in patients with castrate-resistant prostate cancer.	Aurelius Omlin	16.04.2019
SAKK 01/18	Reduced intensity radiochemotherapy for Stage IIA/B Seminoma.	Alexandros Papachristofilou	11.07.2019
SAKK 06/17	Neoadjuvant and adjuvant durvalumab in combination with neoadjuvant chemotherapy in patients with operable urothelial cancer. A multicenter, single-arm phase II trial.	Richard Cathomas	15.05.2018
SAKK 07/17	Nivolumab in combination with Ipilimumab in patients with metastatic renal cell carcinoma: A multicenter single-arm phase II trial.	Frank Stenner	13.12.2017
SAKK 08/14	Investigation of Metformin in patients with castration resistant Prostate Cancer in combination with Enzalutamide vs. Enzalutamide alone (IMPROVE TRIAL) A randomized, open label, phase II trial.	Christian Rothermundt	20.05.2016
SAKK 08/15	Multicenter, Randomized Phase II Trial of Salvage Radiotherapy +/- Metformin for Patients with Prostate Cancer after Prostatectomy.	Daniel M. Aebersold	22.09.2017
SAKK 08/16	ODM-201 maintenance therapy in patients with metastatic castration resistant prostate cancer (mCRPC) previously treated with novel hormonal agents and non-progressive disease after subsequent treatment with a taxane: A multicenter randomized double-blind placebo-controlled phase II trial.	Silke Gillessen	31.03.2017
SAKK 09/18	Extended pelvic lymph node dissection vs. no pelvic lymph node dissection at radical prostatectomy for intermediate- and high-risk prostate cancer: An international, multicenter,randomized phase III trial.	Cyrill Rentsch	11.07.2019
SAKK 63/12	Prospective cohort study with collection of clinical data, serum and plasma of patients with prostate disease.	Daniel Engeler	15.10.2014
SAKK 96/12	Prevention of Symptomatic Skeletal Events with Denosumab Administered every 4 Weeks versus every 12 Weeks – A Non-Inferiority Phase III Trial.	Roger von Moos	16.07.2014
STAMPEDE	Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy A multi-arm multi-stage randomised controlled trial.	George Thalmann	11.01.2010

Trials closed for accrual in 2019

Trial name	Trial title	Coordinating investigator	Activation
Breast Cancers			
IBCSG 48-14 POSITIVE	A study evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy (POSITIVE).	Olivia Pagani	31.12.2019
IBCSG 50-14 OLYMPIA	A randomised, double-blind, parallel group, placebo-controlled multi-centre Phase III study to assess the efficacy and safety of olaparib vs placebo as adjuvant treatment in patients with high risk germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy.	Urban Novak	28.05.2019
SAKK 24/14	Anti-EGFR-immunoliposomes loaded with doxorubicin in patients with advanced triple negative EGFR positive breast cancer - A multicenter single arm phase II trial.	Ralph Winterhalder	29.10.2019
SAKK 25/14	Eribulin as 1st line treatment in elderly patients (>= 70 years) with advanced breast cancer: a multicenter phase II trial.	Ursula Hasler-Strub	26.02.2019
Leukemias			
CLL13	A phase 3 multicenter, randomized, prospective, open-label trial of standard chemoimmunotherapy (FCR/BR) versus rituximab plus venetoclax (RVe) versus obinutuzumab (GA101) plus venetoclax (GVe) versus obinutuzumab plus ibrutinib plus venetoclax (GIVe) in fit patients with previously untreated chronic lymphocytic leukemia (CLL) without Del(17p) or TP53 mutation.	Michael Gregor	07.11.2019
HOVON 103 - SEL	A randomized phase II multicenter study with a safety run-in to assess the tolerability and efficacy of the addition of oral selinexor (KPT-330) to standard induction chemotherapy in AML and high risk myelodysplasia (MDS) (IPSS-R > 4.5) in patients aged >=66 years.	Georg Stüssi	09.10.2019
Lung Cancers			
ETOP BOOSTER	A randomised phase II trial of osimertinib and bevacizumab versus osimertinib alone as second-line treatment in stage IIIb-IVb NSCLC with confirmed EGFRm and T790M.	Martin Früh	21.02.2019
SAKK 16/14	Anti-PD-L1 antibody MEDI4736 in addition to neoadjuvant chemotherapy in patients with stage IIIA(N2) non-small cell lung cancer (NSCLC). A multicenter single-arm phase II trial.	Sacha Rothschild	17.01.2019
Lymphomas			
IELSG-37	A randomized, open-label, multicentre, two-arm phase III comparative study assessing the role of involved mediastinal radiotherapy after Rituximab containing chemotherapy regimens to patients with newly diagnosed Primary Mediastinal Large B-Cell Lymphoma (PMLBCL).	Emanuele Zucca	06.08.2019
IELSG-43	High-dose chemotherapy and autologous stem cell transplant consolidating conventional chemotherapy in primary CNS lymphoma -randomized phase III trial (Matrix).	Thomas Pabst	04.09.2019
Sarcomas			
EURO EWING 2012	International Randomised Controlled Trial for the Treatment of Newly Diagnosed Ewing's Sarcoma Family of Tumours Euro Ewing 2012.	Attila Kollàr	03.05.2019
Urogenital Cancers			
SAKK 06/17	Neoadjuvant and adjuvant durvalumab in combination with neoadjuvant chemotherapy in patients with operable urothelial cancer. A multicenter, single-arm phase II trial.	Richard Cathomas	27.09.2019

Accrual numbers per disease and member

Breast Cancers	Cancers of Head and Neck	Gastrointestinal Cancers	Gynecological Cancers	Leukemias	Lung Cancers	Lymphomas	New anticancer treatments	Sarcomas	Urogenital Cancers	Totals		
484	**7**	**67**	**15**	**60**	**78**	**167**	**39**	**20**	**398**	**1335**	Member	Sites
13	0	0	0	6	7	5	0	0	4	**35**	**Aargau**	**Kantonsspital Aarau**
21	0	4	1	0	0	1	0	0	8	**35**	**Baden**	**Kantonsspital Baden**
55	1	9	4	4	6	9	0	3	43	**134**	**Basel**	**Basel Bethesda Spital; Brustzentrum Basel – Praxis Thorn; Caba Zentrum für Onkologie, Psychologie und Bewegung; Claraspital; Kantonsspital Baselland Bruderholz; Kantonsspital Baselland Liestal; Onkopraxis Dr. med. A. Dieterle; Universitätsspital Basel**
14	0	2	1	3	10	28	6	3	52	**119**	**Bern**	**Inselspital; Lindenhofgruppe – Engeriedspital; Lindenhofgruppe – Sonnenhofspital**
0	0	0	0	0	0	0	0	0	0	**0**	**Biel**	**Spitalzentrum Biel**
47	0	0	0	0	0	4	0	0	11	**62**	**Fribourg**	**Centre du sein Fribourg/Brustzentrum Freiburg; Hôpital Daler; Hôpital Fribourgeois – Hôpital Cantonal; Hôpital neuchâtelois – La Chaux-de-Fonds; Hôpital neuchâtelois – Neuchâtel; Network – Hôpital Neuchâtelois**
18	0	3	0	3	6	2	3	0	32	**67**	**Genève**	**Clinique des Grangettes; Hôpitaux Universitaires de Genève; Praxis Dr. med E. Tullen; Praxis Dr. med. A. Hügli**
25	0	2	0	2	15	11	4	0	61	**120**	**Graubünden**	**Kantonsspital Graubünden; Tumorzentrum ZeTuP Chur**
56	0	1	0	0	0	1	0	0	7	**65**	**Hirslanden**	**Brustzentrum (Seefeld); Hirslanden Klinik Hirslanden; Hirslanden Klinik Im Park; Hirslandenklinik Aarau; Hirslandenklinik Andreasklinik Cham Zug; Hirslandenklinik St. Anna; Onkologie Bellevue; Spital Zollikerberg; Tumorzentrum Aarau - Hirslanden Medical Center**
9	0	1	0	0	0	0	0	0	15	**25**	**Solothurn**	**Bürgerspital Solothurn – Solothurner Spitäler; Kantonsspital Olten – Solothurner Spitäler**
54	0	6	0	6	17	18	14	4	16	**135**	**St. Gallen**	**Brustzentrum Ostschweiz; Kantonsspital St. Gallen; Rundum Onkologie am Bahnhofpark; Tumor- und Brustzentrum ZeTuP; ZeTuP Rapperswil-Jona**
6	0	0	0	1	1	3	0	0	10	**21**	**Thun**	**Radio-Onkologie Berner Oberland AG; Spital STS AG Thun**
20	0	2	2	4	0	2	0	0	1	**31**	**Thurgau**	**Network – Spital Thurgau; Spital Thurgau - Kantonsspital Frauenfeld; Spital Thurgau – Kantonsspital Münsterlingen**
12	0	6	1	5	4	8	9	2	19	**66**	**Ticino**	**Clinica Luganese; EOC – Istituto Oncologico della Svizzera Italiana; Fondazione Oncologia Lago Maggiore; Oncologia Varini&Calderoni**
11	0	1	0	0	0	0	0	0	3	**15**	**Valais**	**Hôpital du Valais, Hôpital de Sion; Hôpital du Valais, Spital Brig; Network – Hôpitaux du Valais**
19	5	0	0	3	2	3	2	1	6	**41**	**Vaud**	**CCAC – Centre de Chimiothérapie Anti-Cancéreuse; CHUV – Centre hospitalier universitaire vaudois; Clinique de Genolier**
19	0	3	0	4	3	3	0	0	24	**56**	**Winterthur**	**Kantonsspital Winterthur**
8	0	5	2	7	2	12	0	2	4	**42**	**Zentralschweiz**	**Luzerner Kantonsspital Luzern**
7	0	3	0	1	0	3	0	0	8	**22**	**Zürich Triemli**	**Spital Limmattal; Stadtspital Triemli**
16	1	2	4	11	5	9	1	5	8	**62**	**Zürich USZ**	**Spital Männedorf; UniversitätsSpital Zürich**
54	0	17	0	0	0	45	0	0	66	**182**	**Total Foreign Countries**	

Publications by SAKK and Cooperative Groups 2019

Trial name	Trial title	Authors	Journal	IF*
Breast Cancers				
	Prospective Evaluation of Residual Breast Tissue after SKIn- or NIpple-Sparing Mastectomy – Results of the SKINI-Trial.	Papassotiropoulos B, Güth U, Chiesa F, Rageth C, Amann E, Baege A, Elfgen C, Varga Z, Moskovszky L, Endhardt K, Masser R, Tinguely M, Farhadi J, Lardi A, Dammann F, Diebold J, Li Q, Dubsky P, Tausch C	ANN SURG ONCOL	3.93
IBCSG 18-98	Clinical and analytical validation of Ki-67 in 9069 patients from IBCSG VIII+IX, BIG1-98 and GeparTrio trial: systematic modulation of interobserver variance in a comprehensive in silico ring trial.	Denkert C, Budczies J, Regan MM, Loibl S, Dell'Orto P, von Minckwitz G, Mastropasqua MG, Solbach C, Thürlimann B, Mehta K, Blohmer JU, Colleoni M, Müller V, Klauschen F, Ataseven B, Engels K, Kammler R, Pfitzner BM, Dietel M, Fasching PA, Viale G	BREAST CANCER RES TR	3.471
IBCSG 18-98	Prognostic and predictive value of androgen receptor expression in postmenopausal women with estrogen receptor-positive breast cancer: results from the Breast International Group Trial 1-98.	Kensler KH, Regan MM, Heng YJ, Baker GM, Pyle ME, Schnitt SJ, Hazra A, Kammler R, Thürlimann B, Colleoni M, Viale G, Brown M, Tamimi RM	BREAST CANCER RES	3.471
SOFT, TEXT	Absolute Improvements in Freedom From Distant Recurrence to Tailor Adjuvant Endocrine Therapies for Premenopausal Women: Results From TEXT and SOFT.	Pagani O, Francis PA, Fleming GF, Walley BA, Viale G, Colleoni M, Láng I, Gómez HL, Tondini C, Pinotti G, Di Leo A, Coates AS, Goldhirsch A, Gelber RD, Regan MM	J CLIN ONCOL	18.428
SAKK 28/12	Ki-67 assessment in early breast cancer: SAKK28/12 validation study on the IBCSG VIII and IBCSG IX cohort.	Varga Z, Li Q, Jochum W, Perriard U, Rau T, Tille JC, Hawle H, Klingbiel D, Thuerlimann B, Ruhstaller T.	SCI REP	4.525
SAKK 22/99	Long-term responders to trastuzumab monotherapy in first-line HER-2+ advanced breast cancer: characteristics and survival data.	Schmid S, Klingbiel D, Aebi S, Goldhirsch A, Mamot C, Munzone E, Nolè F, Oehlschlegel C, Pagani O, Pestalozzi B, Rochlitz C, Thürlimann B, von Moos R, Weder P, Zaman K, Ruhstaller T.	BMC CANCER	3.362
Head and Neck Cancers				
	A Review of Controversial Issues in the Management of Head and Neck Cancer: A Swiss Multidisciplinary and Multi-Institutional Patterns of Care Study-Part 1 (Head and Neck Surgery).	Dulguerov P, Broglie MA, Henke G, Siano M, Putora PM, Simon C, Zwahlen D, Huber GF, Ballerini G, Beffa L, Giger R, Rothschild S, Negri SV, Elicin O.	FRONT ONCOL	4.25
	A Review of Controversial Issues in the Management of Head and Neck Cancer: A Swiss Multidisciplinary and Multi-Institutional Patterns of Care Study-Part 2 (Radiation Oncology).	Elicin O, Putora PM, Siano M, Broglie MA, Simon C, Zwahlen D, Huber GF, Ballerini G, Beffa L, Giger R, Rothschild S, Negri SV, Dulguerov P, Henke G.	FRONT ONCOL	4.25
	A Review of Controversial Issues in the Management of Head and Neck Cancer: A Swiss Multidisciplinary and Multi-Institutional Patterns of Care Study-Part 3 (Medical Oncology).	Siano M, Dulguerov P, Broglie MA, Henke G, Putora PM, Simon C, Zwahlen D, Huber GF, Ballerini G, Beffa L, Giger R, Rothschild S, Negri SV, Elicin O.	FRONT ONCOL	4.25
	A Review of Controversial Issues in the Management of Head and Neck Cancer: A Swiss Multidisciplinary and Multi-Institutional Patterns of Care Study-Part 4 (Biomarkers).	Broglie MA, Dulguerov P, Henke G, Siano M, Putora PM, Simon C, Zwahlen D, Huber GF, Ballerini G, Beffa L, Giger R, Rothschild S, Negri SV, Elicin O.	FRONT ONCOL	4.25
Gastrointestinal Cancers				
SAKK 40/04	ASO Author Reflections: What is the Impact of Different Rectal Reconstruction Techniques After Total Mesorectal Excision on Quality of Life?	Ribi K, Bernhard J.	ANN SURG ONCOL	3.93
SAKK 40/04	Quality of Life After Total Mesorectal Excision and Rectal Replacement: Comparing Side-to-End, Colon J-Pouch and Straight Colorectal Reconstruction in a Randomized, Phase III Trial (SAKK40/04).	Ribi K, Marti WR, Bernhard J, Grieder F, Graf M, Gloor B, Curti G, Zuber M, Demartines N, Andrieu C, Bigler M, Hayoz S, Wehrli H, Kettelhack C, Lerf B, Fasolini F, Hamel C	ANN SURG ONCOL	3.93
SAKK 44/00	Predicting mortality and adverse events in patients with advanced pancreatic cancer (APC) treated with palliative Gemcitabine-based chemotherapy in a multicentre phase III randomized clinical trial: the APC-SAKK risk scores.	Gargiulo P, Dietrich D, Herrmann R, Bodoky G, Ruhstaller T, Scheithauer W, Glimelius B, Berardi S, Pignata S, Brauchli P	THER ADV MED ONCOL	0.955
SAKK 75/08	Skeletal muscle mass correlates with increased toxicity during neoadjuvant radiochemotherapy in locally advanced esophageal cancer. A SAKK 75/08 Substudy.	Panje CM, Höng L, Hayoz S, Baracos VE, Herrmann E, Garcia Schüler H, Meier UR, Henke G, Schacher S, Hawle H, Gérard MA, Ruhstaller T, Plasswilm L	RADIAT ONCOL	2.546
Leukemias				
GRAALL 2003, GRAALL 2005	Adult T-cell Acute Lymphoblastic Leukemias with IL7R pathway mutations are slow-responders who do not benefit from allogeneic stem-cell transplantation.	Kim R, Boissel N, Touzart A, Leguay T, Thonier F, Thomas X, Raffoux E, Huguet F, Villarese P, Fourrage C, Passini L, Hunault M, Lepretre S, Chevallier P, Braun T, Lhéritier V, Chantepie S, Maury S, Escoffre M, Tavernier E, Chalandon Y, Graux C, Macintyre E, Ifrah N, Asnafi V, Dombret H, Lhermitte L; on behalf the GRAALL group	LEUKEMIA	9.944
GRAALL 2003, GRAALL 2005	Clinical and biological features of PTPN2-deleted adult and pediatric T-cell acute lymphoblastic leukemia.	Alcantara M, Simonin M, Lhermitte L, Touzart A, Dourthe ME, Latiri M, Grardel N, Cayuela JM, Chalandon Y, Graux C, Dombret H, Ifrah N, Petit A, Macintyre E, Baruchel A, Boissel N, Asnafi V	BLOOD ADV	.
Lung Cancers				
	Outcomes with immune checkpoint inhibitors for relapsed Small-Cell Lung Cancer in a Swiss cohort.	Sabine Schmid; Laetitia Mauti; Alex Friedlaender; Veronika Blum; Sacha Rothschild; Hasna Bouchaab Bouchaab; Patrizia Frösch; Christian Britschgi; David König; Luciano Wannesson; Wolf-Dieter Janthur; Sämi Schär; Izadora Demmer; Alfredo Addeo Addeo; Wolfram Jochum; Martin Früh	CANCER IMMUNOL IMMUN	4.9

Trial name	Trial title	Authors	Journal	IF*
	Patterns of progression on osimertinib in EGFR T790M positive NSCLC: A Swiss cohort study.	Schmid S, Klingbiel D, Aeppli S, Britschgi C, Gautschi O, Pless M, Rothschild S, Wannesson L, Janthur W, Foerbs D, Demmer I, Jochum W, Früh M	LUNG CANCER	3.958
ETOP BELIEF	Evolution and clinical impact of EGFR mutations in circulating free DNA in the BELIEF trial.	Molina-Vila MA, Stahel RA, Dafni U, Jordana-Ariza N, Balada-Bel A, Garzón-Ibáñez M, García-Peláez B, Mayo-de-Las-Casas C, Felip E, Fontecedro AC, Gautschi O, Peters S, Massutí B, Palmero R, Aix SP, Carcereny E, Früh M, Pless M, Popat S, Cuffe S, Bidoli P, Kammler R, Roschitzki-Voser H, Tsourti Z, Karachaliou N, Rosell R	J THORAC ONCOL	5.282
SAKK 16/08	Preoperative chemotherapy and radiotherapy concomitant to cetuximab in stage IIIB NSCLC. A multicenter phase II trial (SAKK 16/08).	Curioni-Fontecedro A, Perentes JY, Gelpke H, Xyrafas A, Bouchaab H, Mach N, Matzinger O, Stojcheva N, Frueh M, Weder W, Cathomas R, Gargiulo P, Bubendorf L, Pless M, Betticher D, Peters S	BR J CANCER	5.282
SAKK 17/16	Lurbinectedin as second- or third-line palliative chemotherapy in malignant pleural mesothelioma: an international, multi-centre, single-arm, Phase II trial.	Metaxas Y, Früh M, Eboulet E I, Grosso F, Pless M, Zucali P A, Ceresoli G L, Mark M, Schneider M, Maconi A, Perrino M, Biaggi-Rudolf C,. Froesch P, Schmid S, Waibel C, Appenzeller C, Rauch D, von Moos R	ANN ONCOL	14.196
SAKK 17/04	Pattern of Failure after Adjuvant Radiotherapy Following Extrapleural Pneumonectomy of Pleural Mesothelioma in the SAKK 17/04 Trial.	Riesterer O, Frank Ciernik I, Stahel RA, Xyrafas A, Aebersold DM, Plasswilm L, Mahmut Ozsahin E, Zwahlen DR, Nackaerts K, Zimmermann F, Sabrina Stark L, Weder W, Krayenbuehl J	RADIOTHER ONCOL	4.363
SAKK 17/04	miR-625-3p and lncRNA GAS5 in Liquid Biopsies for Predicting the Outcome of Malignant Pleural Mesothelioma Patients Treated with Neo-Adjuvant Chemotherapy and Surgery.	Kresoja-Rakic J, Szpechcinski A, Kirschner MB, Ronner M, Minatel B, Martinez VD, Lam WL, Weder W, Stahel R, Früh M, Cerciello F, Felley-Bosco E.	NON-CODING RNA	
Lymphomas				
HD 16	Positron Emission Tomography-Guided Treatment in Early-Stage Favorable Hodgkin Lymphoma: Final Results of the International, Randomized Phase III HD16 Trial by the German Hodgkin Study Group.	Fuchs M, Goergen H, Kobe C, Kuhnert G, Lohri A, Greil R, Sasse S, Topp MS, Schäfer E, Hertenstein B, Soekler M, Vogelhuber M, Zijlstra JM, Keller UB, Krause SW, Wilhelm M, Maschmeyer G, Thiemer J, Dührsen U, Meissner J, Viardot A, Eich H, Baues C, Diehl V, Rosenwald A, von Tresckow B, Dietlein M, Borchmann P, Engert A.	J CLIN ONCOL	18.428
REMoDL-B	Gene-expression profiling of bortezomib added to standard chemoimmunotherapy for diffuse large B-cell lymphoma (REMoDL-B): an open-label, randomised, phase 3 trial.	Davies A, Cummin TE, Barrans S, Maishman T, Mamot C, Novak U, Caddy J, Stanton L, Kazmi-Stokes S, McMillan A, Fields P, Pocock C, Collins GP, Stephens R, Cucco F, Clipson A, Sha C, Tooze R, Care MA, Griffiths G, Du MQ, Westhead DR, Burton C, Johnson PWM	LANCET ONCOL	24.69

Trial name	Trial title	Authors	Journal	IF*
SAKK 35/10	Randomized Phase-2 Trial SAKK 35/10: Rituximab Plus Lenalidomide Versus Rituximab Monotherapy in Untreated Follicular Lymphoma Patients in Need of Therapy.	Zucca E, Rondeau S, Vanazzi A, Østenstad B, Mey UJM, Rauch D, Wahlin BE, Hitz F, Hernberg M, Johansson AS, de Nully Brown P, Hagberg H, Ferreri AJM, Lohri A, Novak U, Zander T, Bersvendsen H, Bargetzi M, Mingrone W, Krasniqi F, Dirnhofer S, Hayoz S, Hawle H, Berardi Vilei S, Ghielmini M, Kimby E	BLOOD	10.452
SAKK 39/10	Nelfinavir and Lenalidomide/Dexamethasone in Patients with Lenalidomide-Refractory Multiple Myeloma. A Phase I/II Trial (SAKK 39/10).	Hitz F, Kraus M, Pabst T, Hess D, Besse L, Silzle T, Novak U, Seipel K, Rondeau S, Stüdeli S, Vilei SB, Samaras P, Mey U, Driessen C	BLOOD CANCER J	8.125
SAKK 35/10	Prognostic implications of the microenvironment for follicular lymphoma under immunomodulation therapy.	Menter T, Tzankov A, Zucca E, Kimby E, Hultdin M, Sundström C, Beiske K, Cogliatti S, Banz Y, Cathomas G, Karjalainen-Lindsberg ML, Grobholz R, Mazzucchelli L, Sander B, Hawle H, Hayoz S, Dirnhofer S	BRIT J HAEMATOL	5.206
New Anticancer Treatments				
SAKK 67/15	A Phase 1 study of BAL101553, a novel tumor checkpoint controller targeting microtubules, administered as 48-h infusion in adult patients with advanced solid tumors.	Joerger M, Stathis A, Metaxas Y, Hess D, Mantiero M, Mark M, Volden M, Kaindl T, Engelhardt M, Larger P, Lane H, Hafner P, Levy N, Stuedeli S, Sessa C, von Moos R.	INVEST NEW DRUGS	2.919
Radio-Oncology				
	Predictive factors for response to salvage stereotactic body radiotherapy in oligorecurrent prostate cancer limited to lymph nodes: a single institution experience.	Oehler C, Zimmermann M, Adam L, Curschmann J, Sumila M, Strebel RT, Cathomas R, Li Q, Schneider U, Zwahlen DR.	BMC UROL	1.792
Supportive Care				
SAKK 95/16	Patterns of care for patients with metastatic bone disease in solid tumors – a cross-sectional study (SAKK 95/16).	Mark M, Thürlimann B, Ribi K, Schär C, Dietrich D, Cathomas R, Zürrer-Härdi U, von Briel T, Anchisi S, Bohanes P, Blum V, von Burg P, Mannhart M, Caspar CB, von Moos R	J BONE ONCOL	2.886
Urogenital Cancers				
	Characteristics and treatment outcomes of 1,375 localized and metastatic testicular Leydig cell tumors: a systematic literature review and meta-analysis.	Fankhauser CD, Grogg JB, Hayoz S, Wettstein MS, Dieckmann KP, Sulser T, Bode PK, Clarke NW, Beyer J, Hermanns T.	J UROLOGY	5.647
	Impact of Addition of Metformin to Abiraterone in Metastatic Castration-Resistant Prostate Cancer Patients With Disease Progressing While Receiving Abiraterone Treatment (MetAb-Pro): Phase 2 Pilot Study.	Mark M, Klingbiel D, Mey U, Winterhalder R, Rothermundt C, Gillessen S, von Moos R, Pollak M, Manetsch G, Strebel R, Cathomas R.	CLIN GENITOURIN CANCER	2.45
	Shared decision making for patients with advanced urological malignancies – Evaluation of a joint urological-oncological clinic model.	Betschart P, Babst C, Schmid S, Rothermundt C, Abt D, Schwab C, Gillessen S, Engeler DS, Klingbiel D, Schmid HP, Omlin A	ONCOL RES TREAT	1.09

Trial name	Trial title	Authors	Journal	IF*
STAMPEDE	Abiraterone in "High-" and "Low-risk" Metastatic Hormone-sensitive Prostate Cancer.	Hoyle AP, Ali A, James ND, Cook A, Parker CC, de Bono JS, Attard G, Chowdhury S, Cross WR, Dearnaley DP, Brawley CD, Gilson C, Ingleby F, Gillessen S, Aebersold DM, Jones RJ, Matheson D, Millman R, Mason MD, Ritchie AWS, Russell M, Douis H, Parmar MKB, Sydes MR, Clarke NW	EUR UROL	13.938
SAKK 08/14	Analysis of AR/ARV7 Expression in Isolated Circulating Tumor Cells of Patients with Metastatic Castration-Resistant Prostate Cancer (SAKK 08/14 IMPROVE Trial).	Hench IB, Cathomas R, Costa L, Fischer N, Gillessen S, Hench J, Hermanns T, Kremer E, Mingrone W, Mestre RP, Püschel H, Rothermundt C, Ruiz C, Tolnay M, Burg PV, Bubendorf L, Vlajnic T	CANCERS	5.326

Presentation of SAKK Trials (Without Cooperative Groups)

American Society of Clinical Oncology (ASCO) Annual Meeting

Poster

Salvatore L. et al. Bevacizumab (BV) maintenance (M) after first-line chemotherapy (CT) plus BV for metastatic colorectal cancer (mCRC) patients (pts): a meta-analysis of individual pts data (IPD) from 3 phase III studies

American Society of Clinical Oncology Genitourinary Cancers (ASCO GU) Annual Meeting

Oral presentation

Gillessen S. et al. Incidence of hypocalcemia (HC) in patients with castration resistant prostate cancer treated with denosumab (DN): Data from a non-inferiority phase III trial assessing prevention of symptomatic skeletal events (SSE) with DN administered every 4 weeks (q4w) versus every 12 weeks (q12w): SAKK 96/12 (REDUSE)

American Society of Hematology (ASH) Annual Meeting

Poster

Stojkov K. et al. I-CARE for MDS: Development of Guidelines-Based Indicators for Appropriate Care in Adult Patients with Myelodysplastic Syndromes

American Society for Radiation Oncology (ASTRO) Annual Meeting

Poster

Carol O. et al. PET radiomics model based on multicentric imaging data to predict event-free survival in locally advanced non-small cell lung cancer

18th Acta Oncologica conference on biology-guided adaptive radiotheray (BiGART)

Poster

Vuong D. et al. Comparison of robust to standardized CT radiomics models to predict OS for NSCLC patients

European Congress of Pathology

Oral presentation

Menter T. et al. Prognostic role of the microenvironment in follicular lymphoma treated with rituximab and rituximab+lenalidomide – results of a translational study of the SAKK35/10 trial

European Lung Cancer Congress (ELCC)

Poster

Vuong D. et al. Standardization of CT image protocols is superior to using larger but heterogeneous CT image datasets for robust radiomics-based modeling

European Society for Medical Oncology (ESMO) Congress

Oral presentation

Metaxas I. et al. Lurbinectedin Monotherapy in Patients with Progressive Malignant Pleural Mesothelioma. A Multicenter, Single-arm Phase II Trial

Poster

Digklia A. et al. SAKK 57/16 Nab-Paclitaxel and Gemcitabine in soft tissue sarcoma (NAPAGE): results from the phase I part of a phase I/II trial

Poster

Mark M. et al. Patterns of care for patients with metastatic bone disease in solid tumors – a cross-sectional study (SAKK 95/16)

European Society for Medical Oncology (ESMO) Breast Cancer Annual Congress

Oral presentation

Huober J. et al. Pertuzumab (P) + trastuzumab (T) with or without chemotherapy both followed by T-DM1 in case of progression in patients with HER2-positive metastatic breast cancer (MBC)- The PERNETTA trial (SAKK 22/10), a randomized open label phase II study (SAKK, UNICANCER, BOOG)

Poster
Vetter M. et al. SAKK 21/12 - A stratified, multicenter Phase II trial of transdermal CR1447 (4-OH-testosterone) in endocrine responsive-HER2 negative and triple negative-androgen receptor positive metastatic or locally advanced breast cancer.

The European Society for Radiotherapy and Oncology (ESTRO) 38

Poster
Vuong D. et al. CT image standardization is superior to larger but heterogeneous datasets for robust radiomic models

International Conference on Malignant Lymphoma (ICML)

Oral presentation
Ceriani L. et al. Integration between metabolic tumour value and metabolic heterogeneity predicts outcome in DLBCL lymphoma patients SAKK 38/07 study cohort

Oral presentation
Menter T. et al. Prognostic implications of the microenvironment in follicular lymphoma under rituximab and rituximab+lenalidomide therapy; results of the translational study to the SAKK35/10 trial

Oral presentation
Moccia A. et al. Predictive value of POD24 validation in follicular lymphoma patients initially treated with chemotherapy-free regimens in a pooled analysis of three randomized trials of the Swiss Group for Clinical Cancer Research (SAKK)

Oral presentation
Stathis A. et al. SAKK 35/15: A phase I trial of obinutuzumab in combination with venetoclax in previously untreated follicular lymphoma patients

Master of Disaster State of the Art Therapy and Complication Management in Gynecologic Oncology and Breast Cancer

Oral presentation
Weber W. et al. New Markers and Techniques for Lymph Node Detection

Scientific Association of Swiss Radiation Oncology (SASRO) Annual Meeting

Poster discussion
Vuong D. et al. CT based lymph nodes radiomics to predict 12-months event-free survival in stage IIIA NSCLC; SAKK 16/00

Poster
Panje C. et al. Skeletal muscle mass correlates with increased toxicity during neoadjuvant radiochemotherapy in locally advanced esophageal cancer. A SAKK 75/08 Substudy.

Joint Annual Meeting of the Swiss and Austrian Societies of Pathology and the Swiss Society of Cytology (SGPATH-ÖGPATH-SSCYT)

Oral presentation
Menter T. et al. Prognostic implications of the microenvironment for follicular lymphoma under immunomodulative therapy by lenalidomide – results of a translational study of the SAKK35/10 trial

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