Annual report 2020

SAKK
WE BRING PROGRESS TO CANCER CARE

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Inhalt

Prof. Dr. med. Roger von Moos
SAKK President

Prof. Dr. med. Miklos Pless
SAKK Vice President

Dear Friends and Colleagues,

2020 will be remembered as an eventful year in the history of SAKK, one that was full of ups and downs. It began with ambitious plans and a start that indicated that the number of open trials and participating patients might surpass the figures in previous years. Operational activities were booming. The flagship projects Working Group Cellular Therapies and Swiss Centralized Oncology Real World Evidence Data (SCORED) were developing splendidly.

At the strategic level, Prof. Dr. med. Ludwig Plasswilm decided to step down from the SAKK Board at the end of 2019 after 4 years of active participation. As a member of the Board and an expert in the Radio-Oncology section, he always made a valuable contribution to SAKK. Not least, his project "Radiation quality assurance for SAKK trials" has contributed significantly to quality assurance in clinical trials. To succeed Dr. Plasswilm, radio-oncologist Dr. med. Thomas Zilli of Geneva University Hospital was elected to the Board.

Then came the first wave of the COVID-19 pandemic. The necessary measures to deal with the impact on patients, trials, and events were rapidly taken. Risk-based guidelines for handling SAKK trials were produced, guidance on working with cancer patients and their ability to work was produced, and SAKK events were moved to virtual and hybrid formats at lightning speed. The safety of patients in SAKK trials was ensured at all times, despite COVID, and SAKK events and meetings continued to be held in an adapted form.

With great enthusiasm the SAKK Board and Executive Board conducted a strategy review and developed the SAKK strategy 2021+. The strategy identified six future-oriented fields of action: (i) Portfolio development and positioning of SAKK, (ii) Strengthening of collaborations and the network, (iii) Modern infrastructure and systems, (iv) Best-qualified employees, (v) High quality and efficient processes, and (vi) Financial sustainability. For each of these areas, a strategic objective and four to six subsidiary objectives were developed. An implementation plan was drawn up with a timetable, milestones, and performance indicators.

The mood of enthusiasm and renewal generated by the strategy process subsequently gave way to a more sobering assessment. It became clear in the fall that SAKK was in structural financial difficulties of unprecedented proportions. The structural deficit is due to the growth strategy that was adopted a few years ago. The number of open trials rose by 55 % from 2015 to 2019. Many of the trials are academic, patient-oriented trials. SAKK overestimated the volume of funds it could raise from third parties to meet the financial requirements for these trials, and this led to a constantly growing deficit.

PD Dr. Martin Reist
SAKK CEO

Consequently, SAKK will have to drastically reduce its expenditures in the coming years. It has developed a restructuring plan that was approved by the SAKK Board on November 14, 2020. The restructuring involves reducing payments to member institutions (patient fees), reducing trial activities (closure or suspension of trials), suspending infrastructure projects, and eliminating 25 jobs at the SAKK Coordinating Center. In the restructuring plan, great care was taken to retain as many trials as possible and to protect patients from negative impacts. Thanks to this rapid and resolute action and the transparency demonstrated by SAKK, the confidence of relevant sponsors could be maintained and funding for 2021 and beyond assured.
The fact that SAKK has been rescued financially as things stand today must not be allowed to blind us to the substantial damage that the tough restructuring measures have caused. The task facing us now is to restore cohesion both within SAKK and with international groups. The financial restructuring must be followed by a review and a reform of the organizational and management structure of SAKK. This is the only way for SAKK to return to a successful path on a lasting basis and, as a stronger network, to continue to promote clinical cancer research projects for the benefit of patients and to organize training courses and events at all levels.

Prof. Dr. med.
Roger von Moos
SAKK President

Prof. Dr. med.
Miklos Pless
SAKK Vice President

PD Dr. Martin Reist
SAKK CEO

February

SAKK at ASCO GU

The Genitourinary Cancers Symposium of the American Society of Clinical Oncology (ASCO) took place in San Francisco from February 13–15. Two SAKK trials were accepted for poster display sessions:

- Alexandros Papachristofilou et al.: Treatment compliance and early toxicity in SAKK 01/10: Single-dose carboplatin and involved-node radiotherapy for treatment of stage IIA/B seminoma
- Richard Cathomas et al.: Perioperative chemo-immunotherapy with durvalumab (Durva) in combination with cisplatin/gemcitabine (Cis/Gem) for operable muscle-invasive urothelial carcinoma (MIUC): Preplanned interim analysis of a single-arm phase II trial (SAKK 06/17)

7th Introductory Course in Genetic Counseling in Oncology

The Introductory Course in Genetic Counseling in Oncology took place at St.Gallen University of Applied Sciences on February 28 and 29. This official SAKK postgraduate training event is organized every year under the auspices of the SAKK Network for Cancer Predisposition Testing and Counseling. The course is designed for physicians working in various specialties, genetics specialists, nurses, and other specialists involved in genetic counseling in oncology.

May/June

SAKK at the ASCO Virtual Meeting

The following SAKK lung cancer trial was accepted for the poster discussion session at the ASCO Meeting from May 29–31:

Sacha Rothschild et al.: SAKK 16/14: Anti-PD-L1 antibody durvalumab in addition to neoadjuvant chemotherapy in patients with stage IIIA(N2) non-small cell lung cancer (NSCLC) – A multicenter single-arm phase II trial.

Chicago in the (cloudy) Mountains

The COVID-19 pandemic made it impossible to hold the Chicago in the Mountains Meeting from May 31–June 1 at the historic Hotel Paxmontana in Flüeli-Ranft as planned. In its place, we set up a professional studio for the event and transmitted it live and virtually from the SAKK Coordinating Center in Bern. Thanks to switching to a hybrid format, the most important content from the scientific program of the Annual Meeting of the American Society of Clinical Oncology (ASCO) was presented and discussed.

August

14th Swiss PostASCO

SAKK organizes the annual Swiss PostASCO event in Switzerland to enable easy access to scientific news and state of the art interpretation of new data. The 2020 event was held on August 20 with some 100 participants at the Wankdorf Stadium in Bern in compliance with COVID-19 safety guidelines. Nationally renowned speakers, experts, and young scientists presented the data from the ASCO 2020 Virtual Meeting along with their interpretation. The audience of specialists appreciated the opportunity to participate actively and on-site in the discussions.

September

Swiss Hematology Workshop

SAKK hosted the sixth Swiss Hematology Workshop (SHW) on September 16, this time in a fully virtual format. The SHW is an established platform for all clinical hematologists and presents a program of renowned international speakers.

1st ESMO in the Alps

Thanks to the initiative of the established Chicago in the Mountains Meeting Steering Committee, SAKK was quickly able to organize a meeting parallel to the ESMO Virtual Congress 2020: "ESMO in the Alps," held from September 21–22. With a

hybrid format, a live meeting and a live broadcasted webinar presented selected highlights of the ESMO to a total of 120 participants.

SAKK at the ESMO Virtual Congress
The following SAKK trials were presented at the Annual Congress of the European Society for Medical Oncology (ESMO) from September 19–21, 2020:

Oral presentation Joerger M. et al. SAKK 80/20: Outcome and prognostic factors of SARS CoV-2 infection in cancer patients: A cross-sectional study

Oral presentation Rothschild S. et al. SAKK 16/14: Anti-PD-L1 antibody durvalumab in addition to neoadjuvant chemotherapy in patients with stage IIIA(N2) non-small cell lung cancer (NSCLC) – A multicenter single-arm phase II trial

Poster Früh M. et al. SAKK 19/16: Binimetinib, pemetrexed (Pem) and cisplatin (Cis), followed by maintenance of Binimetinib and Pem in patients with advanced non-small cell lung cancer (NSCLC) and KRAS mutations. The phase 1B SAKK 19/16 trial. Speaker: Patrizia Froesch.

Poster Hasler-Strub U. et al. SAKK 25/14: Optimal Dose of Eribulin as 1st Line Treatment in Elderly Patients ≥ 70 Years with Advanced Breast Cancer: A Multicenter phase II Trial

Poster Hess D. et al. SAKK 65/16: TLD-1, a novel liposomal doxorubicin, in patients (pts) with advanced solid tumors: dose escalation part of a multicenter open-label phase I trial

Poster Ribi K. et al. SAKK 95/16: Quality of life and pain in patients with metastatic bone disease from solid tumors treated with bone-targeted agents – a real-world cross-sectional study from Switzerland

Poster Stenner F. et al. SAKK 07/17: Optimizing Ipilimumab in RCC – Results from the SAKK 07/17 Nivolumab (N) + Ipilimumab (I) in mRCC

1st Swiss Post ESMO by SAKK Young Oncology Academy
SAKK organized the first Swiss Post ESMO Meeting on September 25; it was implemented virtually by the participants of the SAKK Young Oncology Academy (YOA) 2020. Nine young, ambitious doctors presented and interpreted the most important data from the ESMO Congress with the support of their YOA mentors. The presentations were recorded and made available on the SAKK website.

Pink Ribbon Fundraising Event
Once again, the proceeds from the Pink Ribbon event are funding a SAKK trial. In 2019 the event supported SAKK trial 95/17 WISE; in 2020 the Pink Ribbon Music Gala on September 26 raised CHF 95,200 for SAKK trial 23/18 – VISION I, which aims to provide breast cancer patients with more gentle treatment.

November

SAKK Winter Semi-Annual Meeting
The SAKK winter semi-annual meeting took place virtually from November 19–21, tying in with the Swiss Oncology and Hematology Congress (SOHC). SAKK project groups, working groups, and sections met at the event to discuss and elaborate proposals for trials. As usual, the meeting offered various training and continuing education opportunities for investigators, study coordinators, and other health care professionals working in clinical research. In addition, the SAKK Patient Advisory Board hosted a patient forum on "Diagnosed with prostate cancer: The latest research findings for patients," designed specifically for patients, their families, and the general public.

Young Oncology Academy

The SAKK Young Oncology Academy was organized for the fourth time in 2020. Nine young doctors benefited from this support and mentoring program, taking part in virtual congresses, postgraduate training at phase I sites, and courses on writing presentations and medical papers. As part of the program, the mentees wrote Post ESMO/EHA/ESTRO review papers and abstracts that were presented at the Post ESMO Meeting and in the Highlights of the Year session of the SAKK winter semi-annual meeting to an audience of experts. The Young Oncology Academy was a resounding success despite the difficult conditions imposed by the COVID-19 pandemic.

December

1st Swiss SMASH

SAKK organized and held the 1st Swiss SMASH (SAKK Meets the hemato-oncological abstracts of ASH) on December 9–10. Fourteen renowned experts in the fields of MDS/AL, PCD, CLL/lymphoma, and MPN summarized and discussed the major news from the Annual Meeting of the American Society of Hematology (ASH) over a two-day period. As a hybrid event, the SAKK SMASH is likely to become a popular postgraduate training event for both specialists and physicians in office practice in the coming years.

Prize Awards

SAKK/Astellas GU-Oncology Award

The SAKK/Astellas GU-Oncology Award focuses on specific improvements in patient management and the results of treatment for urogenital cancers. The SAKK/Astellas GU Oncology Award 2020 went to Dr. Anke Augspach at Bern University for her project, "Role of specialized composition of SWI/SNF complexes in prostate cancer lineage plasticity."

SAKK/Celgene HEM Pioneer Grant

The SAKK/Celgene Grant 2020 for pioneering ideas to combat leukemia was awarded to Dr. med. Mattia Rizzi at Lausanne University Hospital (CHUV) for his project, "Prediction of thrombo-hemorrhagic complications in children with acute lymphoblastic leukemia and lymphoblastic lymphoma: the role of novel global hemostasis assays."

SAKK/Novartis Together for Patients Award
Der SAKK/Novartis Together for Patients Award 2020 was awarded to Dr. med. Ricardo Pereira Mestre at Istituto Oncologico della Svizzera Italiana (IOSI) for the research project, "A pilot project for the introduction of continuous monitoring of vital signs for the health assessment and early detection of clinical deterioration of SARS-CoV-2 infected hematological and oncological patients."

The award is endowed with CHF 30,000 and encourages the continuation of patient-focused research activities.

SAKK/Dr. Paul Janssen Fellowship
The SAKK/Dr. Paul Janssen Fellowship 2020, an educational grant of CHF 30,000, was awarded to Dr. med. Andreas Schmitt at Basel University Hospital. Its purpose is to give young doctors the opportunity to spend up to four months at a renowned research institute abroad where they can develop their knowledge of clinical cancer research and acquire the tools they need to conduct trials successfully.

Project Group Breast Cancer

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

With an accrual of 565 patients during 2020, the Project Group Breast Cancer succeeded in enrolling even more patients in clinical trials (all of them interventional trials) than in previous years. The large majority (440 patients) came from Swiss sites, including 48 hospitals and oncology practices. Our members from other countries accrued 125 patients, mainly in the TAXIS trial. In SCORED registry studies (SAKK 80/19 AlpineTIR and SAKK 80/20 CaSA), the group was able to enroll an additional 78 patients.

The TAXIS trial (**SAKK 23/16**) is a large phase III trial with 1,500 patients. It is a surgical trial that 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). Swiss sites contributed 107 patients; sites abroad in Hungary, Germany, Austria, and Lithuania another 119 patients.

The trial with the highest accrual number this year was the WISE trial (**SAKK 95/17**); this randomized phase III trial looks at the effect of a 24-week activity program (monitored by a tracking device) on aromatase inhibitor induced arthralgia. We were able to include 204 patients this year. The accrual for this trial was overwhelmingly fast; we reached the target of 350 patients more than a year ahead of schedule.

As in former years, we succeeded in enrolling a substantial number of patients (92 patients) in the REDUSE trial (**SAKK 96/12**), which investigates the optimal dosing of denosumab in bone metastasis.

The **SAKK 21/18** trial looks at the efficacy of a ribociclib-endocrine combination vs. chemotherapy in patients with visceral metastatic breast cancer; in this trial, we included 14 patients.

For the newly opened trial VISION I (**SAKK 23/18**) we have already accrued 7 patients. This trial investigates, in patients with complete remission (confirmed by imaging) after neoadjuvant chemotherapy, whether residual microscopic disease can be detected by means of biopsies with sufficient sensitivity. If this trial reaches its endpoint, it would be the basis for a further generation of trials that will aim at treating patients with complete remission after neoadjuvant chemotherapy without surgery.
Our group is a member of the International Breast Cancer Study Group (IBCSG) and the Breast International Group (BIG). We contributed 6 patients to **IBCSG 59-19 POLAR**, which looks at adjuvant palbociclib in patients with a resected loco-regional relapse, and 11 patients to **IBCSG 55-17 TOUCH**, which investigates a chemotherapy free regimen in postmenopausal patients with early Her2-positive breast cancer.

In 2020, there were 6 **publications** in peer-reviewed journals (one from SAKK 22/99, four from IBCSG trials, and one from a BIG trial). There were contributions at major international **conferences**: one poster discussion session (TAXIS) and two posters (TAXIS and SAKK 21/18) at the San Antonio Breast Cancer Conference, as well as three posters at ESMO (SAKK 25/14, SAKK 95/16, SAKK 80/20 CaSA) and ESMO Breast (TAXIS) with researchers from our group.

Project Group Developmental Therapeutics

President: Prof. Dr. med. Dr. phil. nat. Markus Jörger,
Cantonal Hospital St.Gallen
Vice Presidents:
PD Dr. med. Anastasios Stathis,
Oncology Institute of Southern Switzerland (IOSI)
PD Dr. med. Alessandra Curioni-Fontecedro,
Zurich University Hospital
Dr. med. Dr. rer. nat. Christian Britschgi,
Zurich University Hospital

The SAKK Project Group Developmental Therapeutics (PG DT) was launched in November 2019 as the successful merger of the former Project Group New Anticancer Treatments (NAT) and the Working Groups Immuno-Oncology (IO) and Molecular Oncology (MO). This new structure allows us to make optimal use of the expertise of all members, to have strong trials in the immunotherapy and non-immunotherapy field, potential combinations between the two, and strong translational programs. PG DT will have a broadened focus on innovation in oncology as well as an increased member base. Up to 2022, PG DT is headed by the current president (M. Joerger) and vice president (A. Stathis), together with the newly elected (May 2020) second vice presidents, who will focus on immunotherapy (A. Curioni-Fontecedro) and molecular oncology (C. Britschgi), respectively.

2020 was again an active year for PG DT, with the successful launch of **SAKK 66/17**, a trial that combines thermal tumor ablation using a laser system combined with intratumoral injection of the new immune stimulatory compound IP-001 from Immunophotonics, a U.S.-based biotech company. The first two patients were successfully treated at the site in Chur. Two tumor registry trials of the SCORED program were launched in 2020, i.e., **SAKK 80/19** and **SAKK 80/20**, the first with a focus on immunotherapy and the second on COVID-19 in cancer patients. SAKK 80/20 has already completed accrual with 500 patients in Switzerland, and interim results were presented at the ESMO Virtual Congress 2020.

In 2020, 50 patients were enrolled in PG DT trials, including 31 patients in therapeutic trials. PG DT currently supports 7 recruiting phase I(/II) clinical trials in a broad range of tumor entities, including rectal (**SAKK 41/16**), head and neck squamous-cell cancer (**SAKK 11/16**), and lymphoma (**SAKK 66/18**). **SAKK 35/15**, evaluating the combination of the BCL2-inhibitor venetoclax and the anti-CD20 monoclonal antibody obinutuzumab in patients with treatment-naïve follicular lymphoma, completed accrual in February 2019, but intensive negotiations were still ongoing with industry partners and third-party funders in 2019 and 2020 regarding an amendment to a phase I/phase II trial. A follow-up trial of the successfully completed **SAKK 67/15** trial with the tumor checkpoint controller BAL-101553 (Lisavanbulin) from Basilea Pharmaceutica in EB1-positive glioblastoma multiforme patients will be launched in early 2021. A follow-up trial of the still ongoing SAKK 69/17 trial with the oral ATR inhibitor BAY-1895344 in patients with ATM-altered solid tumors and lymphoma will be launched in Q1 2021 (**SAKK 69/20**). **SAKK 65/16**, with the new liposomal doxorubicin compound TLD-1 or Talidox from Bern-based Innomedica, is expected to finalize patient recruitment in the phase I part in Q1 2021 and will continue with a bioequivalence part with participation of 15 patients and a larger registration trial in patients with advanced breast cancer.

Looking ahead in 2021, PG DT is expected to open **SAKK 67/20**, a phase I trial of a new micellar docetaxel compound in patients with castration-resistant prostate cancer (CRPC) in collaboration with Sweden-based Oasmia; **SAKK 17/18**, a combination of atezolizumab and gemcitabine in patients with advanced NSCLC or mesothelioma; a trial with a new anti-ROR1 antibody-drug conjugate from Basel-based NBE Therapeutics in patients with solid tumors; **SAKK 50/20** chemo-immunotherapy in LDH-high melanoma in collaboration with Roche Pharmaceuticals; and a combination of the new diffusion-enhancer INT230-6 from U.S.-based Intensity Therapeutics in combination with a PD1-targeting monoclonal antibody in patients with advanced triple-negative breast cancer (TNBC).

The ongoing financial restructuring of SAKK has also impacted PG DT, as we had to close the "Personalized and cell-based antitumor immunization MVX-ONCO-1 in advanced head and neck squamous cell carcinoma" trial (**SAKK 11/16**); SAKK 11/16 is expected to be relaunched with MaxiVAX as the new sponsor, but conducted by SAKK. As a final and essentially positive note, all negotiations with industry partners in the wake of SAKK's restructuring process were positive, and the respective trials are continuing as planned (SAKK 65/16, SAKK 66/17, SAKK 66/18, SAKK 67/20).

Project Group Gastrointestinal Cancer

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

In addition to the trials that were already ongoing in 2019 (SAKK 41/13, Prodige 32, SAKK 41/16 and SAKK 41/14), a further two trials were activated in 2020:
– the DANTE trial (FLOT ± atezolizumab)
– the SAKK 44/19 trial (IRE in pancreatic cancer)

Although recruitment was suspended from mid-March to the end of May because of the SARS-CoV-2 pandemic, the SAKK Project Group Gastrointestinal Cancer (PG GI) was able to enroll 69 patients in clinical trials in 2020. This number is slightly higher than in the previous year. In SCORED registry studies (SAKK 80/19 AlpineTIR and SAKK 80/20 CaSA), the group was able to enroll an additional 76 patients.

The **SAKK 41/16** trial is an early-stage trial investigating the neoadjuvant use of regorafenib in rectal cancer. This trial has recruited well and was able to determine the planned dosage with the calculated sample size. It will be completed in early 2021.

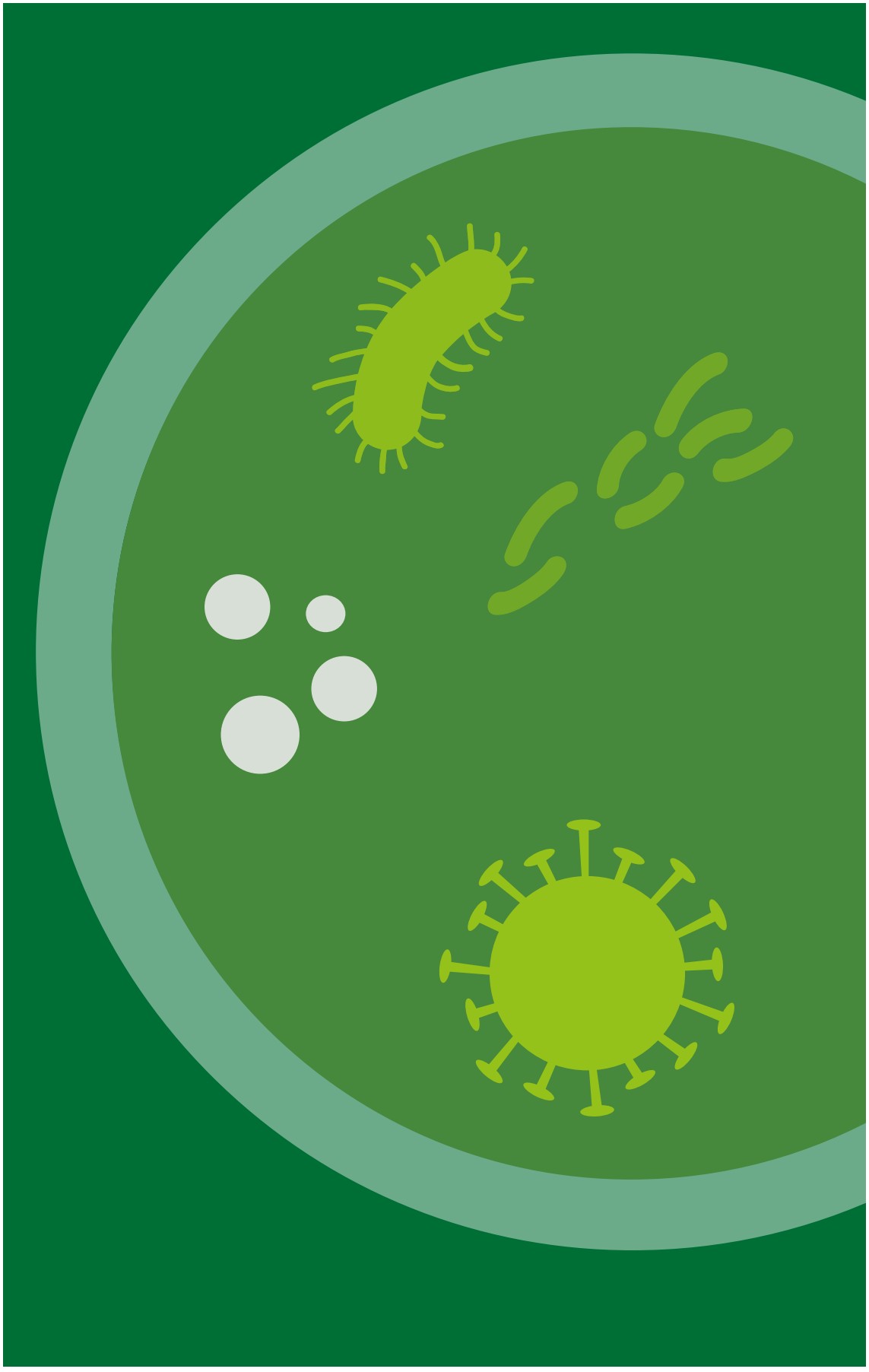
The **DANTE trial** was established in SAKK in cooperation with the Working Group for Internistic Oncology in the German Cancer Society (AIO). This multicenter randomized phase II trial is investigating the use of atezolizumab in conjunction with perioperative FLOT chemotherapy in treatable stomach cancer and esophagogastric junction cancer. DANTE has recruited very well in both Germany and Switzerland, and the full number of patients was already reached in November 2020. The follow-up and translational projects related to the trial will be continued in 2021.

SAKK 44/19 is an innovative, biology-driven trial. It is investigating whether IRE (irreversible electroporation) is capable of modifying the immune environment of pancreatic cancer in such a way that the response to immunotherapy is improved.

SAKK 41/13 (adjuvant aspirin in PIK3CA-mutated CRC), **Prodige 32** (role of surgery in neoadjuvantly treated esophageal cancer), and **SAKK 41/14** (physical activity in patients with mCRC receiving first-line therapy) continued in 2020, apart from the interruption due to COVID-19, with an unchanged recruitment rate.

This year, **two original papers from the PG GI were published**, both describing the completed SAKK 75/08 trial. One paper focused on the analysis of thromboembolic events, the other on surgical outcome data.

Regrettably, SAKK was found to be in serious financial difficulties during the year, in response to which the SAKK Board closed a large number of trials and terminated contracts prematurely. SAKK 41/13, Prodige 32, SAKK 41/14, and SAKK 44/19, mentioned above, were sadly affected by these closures. After several discussions between the investigators, the project group, and the SAKK Board, it has become clear that SAKK 41/14, SAKK 41/13, and Prodige 32 will be terminated definitively. There is unfortunately no way to give adequate recognition to the incredible amount of work and the dedication that has been invested in these trials by the investigators and the trial teams. SAKK 44/19, on the other hand, is being reviewed to establish whether sponsorship can be transferred to enable its continuation from the end of



January 2021. The PG GI supports this signal and will do everything in its power to bring these trials to successful completion.

Unfortunately, the situation described above means that the number of open trials, and thus recruitment numbers, will decrease massively in 2021. The current procedure will also change fundamentally for future trial programs, as full funding must already be available when a trial is proposed. This will substantially limit academically motivated trial programs in particular. To safeguard the future of clinical oncological research in Switzerland, further efforts and a comprehensive restructuring of SAKK and clinical research in oncology will be needed. Trust and credibility are key here, and trust between SAKK and the members must be restored if we are to be successful in a research capacity. Young researchers must have the opportunity to make a career in clinical research, and for this they need transparent and reliable framework conditions. Up to now SAKK has been, in our view, an organization that has successfully supported motivated young researchers. 2020 showed us once again how suddenly unexpected events can turn our lives upside down. Let's work to make the coming years better again!

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)

2020 was a year of new beginnings for the Project Group Leukemia (PG LEUK). An entire generation of new SAKK/HOVON trials for AML (acute myeloid leukemia) patients is in the activation phase. They mark the transition from a "one size fits all" strategy to a personalized concept in the context of curative SAKK/HOVON trials for young fit AML patients. At the same time, they represent the consistently important position of the SAKK PG LEUK within this globally leading AML trial group.

The **SAKK/HOVON 150** protocol was opened for first-line treatment of fit AML patients with a mutation in the IDH1 or IDH2 gene. The **SAKK/HOVON 156** protocol was also activated for first-line treatment of fit AML patients with mutated FLT3. Both protocols are investigating the randomized addition of a specific inhibitor to standard chemotherapy. A third protocol is planned for 2022 for the remaining (triple-negative) AML patients; it will investigate the randomized addition of venetoclax to standard chemotherapy.

The **SAKK/HOVON 155** protocol for first-line palliative therapy is planned for the start of 2021: it will investigate the randomized addition of midostaurin to standard treatment with decitabine. These trials offer an attractive and comprehensive portfolio for first-line treatment of AML patients.

The main contribution to recruitment by the PG LEUK in 2020, however, was made by two trials for CLL patients. The **CLL-13** trial reached its intended recruitment target. It was also possible to complete the **SAKK 34/17** trial (ibrutinib and venetoclax for CLL).

The MDS Registry (**SAKK 33/18** I-CARE) successfully recruited for MDS (myelodysplastic syndrome) patients. Finally, the preparations for a first-line protocol (TIPI protocol) for chronic myeloid leukemia (CML) were successfully advanced.

In SCORED registry study (SAKK 80/20 CaSA), the group was able to enroll an additional 44 patients.

However, as in the other project groups, the restrictions caused by the COVID-19 pandemic and SAKK's financial problems towards the end of the year and the temporary suspension of recruitment into all clinical trials in the Leukemia Group, were significant stumbling blocks in the past year. These problems will unfortunately persist in 2021.

Project Group Lung Cancer

President: PD Dr. med. Martin Früh, Cantonal Hospital St.Gallen
Vice president: Dr. med. Laetitia Mauti,
Cantonal Hospital Winterthur

SAKK Trials for Lung Cancer/Mesothelioma
In 2020, the SAKK Project Group Lung Cancer (PG LU) was active particularly in areas of clinical research defined in the context of a strategy meeting in 2019. These main areas of research comprise early stages (NSCLC stage I-III), NSCLC stage IV, and small cell lung cancer/mesothelioma. In addition, greater emphasis was placed on including younger colleagues in projects, as discussed in 2019. And finally, Laetitia Mauti succeeded Solange Peters as vice president. Solange Peters held this position for many years, and SAKK would like to take this opportunity to thank her once again for the work she did for the group.

Despite the COVID-19 pandemic, the **SAKK 16/18** trial for stage III NSCLC was opened in 2020, following on from SAKK 16/14, which was closed at the start of 2019, and the first patients were successfully recruited. As with **SAKK 16/14**, this is another multimodal treatment concept involving systemic therapy, radiotherapy, and surgery in the age of immunotherapy. The principal investigator is Dr. med. Mauti. The results of SAKK 16/14, which showed a high event-free one-year survival rate of 73 % and a very promising MPR (major pathological response) of 60 %, met with great international acclaim in 2020, and Dr. med. Rothschild was rewarded for his work with oral **presentations** at ASCO, ESMO, and SOHC. Moreover, a number of projects from the older data set of the **SAKK 16** trials for stage III NSCLC are nearing completion. These include an analysis with specific surgical questions by Dr. Furrer and Dr. Weder, and an analysis of the long-term results and the value of biomarkers such as PD-L1 expression by Dr. König and Dr. Früh. Further presentation/publications (poster discussion at the ESTRO European Society for Radiotherapy and Oncology, published in Medical Physics and Frontiers in Oncology) showcased radiomics projects from the SAKK 16/00 trial (Dr. Vuong). 2020 also saw the prominent publication in *Annals of Oncology* of a cost-effectiveness analysis of consolidation immunotherapy with durvalumab in stage III NSCLC responding to definitive radiochemotherapy in a Swiss population, with Dr. Panje as lead author.

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 concluded the expansion cohort at four SAKK phase I sites in Switzerland at the end of 2019 in response to declining patient accrual as new therapeutic options rapidly became available. KRAS mutations make up the major molecular subgroup, accounting for up to 30 % of patients with NSCLC, and the results of this trial were presented by Dr. med. Frösch as a poster at ESMO 2020. The manuscript was submitted for publication.

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 was published in Annals of Oncology in 2020 (lead author Dr. med. Metaxas).

SAKK 19/17, a single-arm phase II trial run by Dr. med. 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 a temporary halt to recruitment, but recruitment is still scheduled for completion during 2021. Dr. Mark successfully published the toxicity data as an interim analysis in *Cancer Immunology, Immunotherapy* in 2020.

2020 also saw the publication by Dr. Amrhein in *Cancer Immunology, Immunotherapy* of an exciting translational data analysis of the influence of tumor microenvironments on chemotherapy, based on tumor samples from the **SAKK 19/09** trial.

The opening of a trial for small cell lung cancer (SCLC) (**SAKK 15/19**) run by Dr. med. Addeo was halted shortly before the expected date for financial reasons; further negotiations with the sponsor are currently ongoing. 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 now scheduled to open in 2021. The impact of early prophylactic cranial irradiation with hippocampal avoidance on neurocognitive function in patients with limited disease small cell lung cancer (**SAKK 15/12**) was published by Dr. Vees in 2020 in *International Journal of Radiation Oncology, Biology, Physics.*

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 therapeutic options was investigated in this selected group. The project was run by Dr. med. Addeo in Geneva. Recruitment was terminated at the end of 2020 in the absence of evidence of relevant efficacy, and presentation of the results at an international congress and their publication is planned for 2021.

Collaborative Trials on Thoracic Cancers

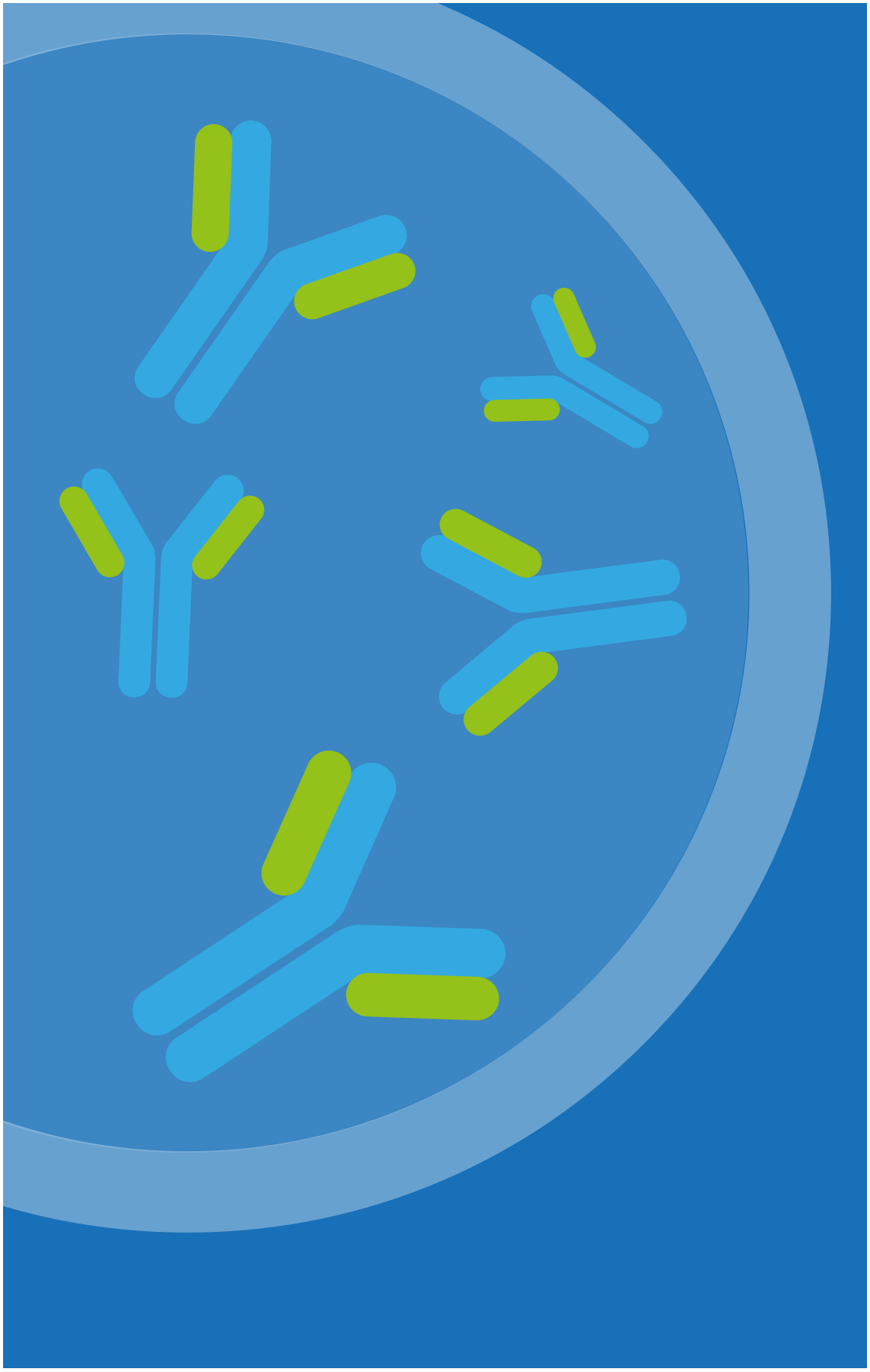
Successful collaboration with the European Thoracic Oncology Platform (ETOP) and the European Organization for Research and Treatment of Cancer (EORTC) continued in 2020. This collaboration is ongoing mainly in the context of major phase III trials and in niche trials for rare indications.

The **ETOP PROMISE-meso** trial, the second trial involving the SAKK Lung Group in patients with mesothelioma in addition to the lurbinectedin trial, was presented in an oral session at ESMO 2019 and published in 2020 in *Annals of Oncology.* **ETOP 13-18 BEAT-meso** (a randomized phase III trial with chemotherapy and bevacizumab and atezolizumab in mesothelioma) was opened in 2019 as a follow-up to the ETOP PROMISE-meso trial, which is recruiting very successfully; recruitment into ETOP 13–18 BEAT-meso is going well at several sites in Switzerland.

SPLENDOUR, a trial investigating the effect of denosumab on overall survival in metastatic NSCLC that was terminated prematurely in response to the rapidly changing treatment landscape, was published in 2020 in *Journal of Thoracic Oncology* with Prof. Peters as the lead author.

The long-awaited data from the **EORTC LungART** trial were presented as a late-breaking abstract at ESMO 2020 and have brought about a paradigm shift, as it can now be clearly demonstrated that postoperative radiotherapy for operated N2-positive NSCLC does NOT confer a survival advantage.

A new and successful collaboration with members of a Scandinavian trial group also began in 2019 with the randomized **ACHILLES** trial (the trial was activated in Switzerland in 2020) to investigate the value of additive atezolizumab following completion of definitive radiochemotherapy in localized SCLC. The trial remains open throughout Switzerland and is recruiting very well.



In 2020, Dr. Schmid and Dr. Mauti moreover published a paper in *Cancer Immunology, Immunotherapy* entitled "Outcomes with immune checkpoint inhibitors for relapsed small-cell lung cancer in a Swiss cohort."

SCORED registry studies
In SCORED registry studies (SAKK 80/19 AlpineTIR and SAKK 80/20 CaSA), the group successfully recruited a large number of patients.

Although at 181 patients the overall recruitment figures were once again slightly lower in 2020 than in the previous year, due in part to COVID and to the small number of trials that were open during a short period of time, 2020 was a successful year on the whole, given the numerous publications/presentations and the many new and interesting (and, in particular, pragmatic) projects that were developed. A number of important and ambitious projects are planned for 2021, particularly in the area of metastatic NSCLC, either in first-line treatment (REPLICA, ctDNA project) or after immunotherapy (ORIGIN).

Project Group Lymphoma

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

In 2020, 173 patients at 20 sites in Switzerland, including all university hospitals, and additional sites abroad were included in a total of 11 clinical trials. We had the new opportunity to offer a registry to our patients with mantle cell lymphoma; 30 % of the patients recruited by the Project Group Lymphoma (PG LYMPH) were recruited for this registry. The group was able to include an additional 31 % of all recruited patients (76 patients) in the SCORED registries (SAKK 80/19 AlpineTIR and SAKK 80/20 CaSA). Given the fact that lymphomas account for only 5 % of all patients with cancer in Switzerland, the achievement of the group, along with the steadily rising numbers over the last years, is most remarkable compared to other SAKK groups. The contribution of the PG LYMPH to academic and, with one exception, all interventional trials is even more impressive considering that these trials enroll patients with rare diseases such as mantle cell lymphoma, CNS lymphomas in elderly frail patients, and Burkitt lymphomas, which are diseases that taken together are diagnosed in fewer than 150 patients per year in Switzerland. For CNS lymphomas, approx. one third of newly diagnosed Swiss patients were included in a clinical trial! Along with the implemented and functioning referrals, this is powerful proof of the commitment of the project group as a whole. In addition, we can be proud that the target accruals for **SAKK 35/14** and **SAKK 36/13** have been reached!

However, in the year of the COVID-19 pandemic, these numbers do not capture the whole picture. Two trials, **SAKK 39/16** and **SAKK 66/18**, were temporarily closed for accrual during the first wave. In the group meetings, however, the members were reminded to not withhold effective therapies for our lymphoma patients.

The scientific output of the group is also outstanding, with five **abstracts** at prestigious meetings in the lymphoma field, and 13 accepted **manuscripts**, including four in top journals (**T-Cell Project, IELSG-42**, and **EMN-02/HOVON 95** in *Lancet Haematology,* and a report on **HD 10** and **HD 13** in *Journal of Clinical Oncology).*

The recently announced significant structural financial problems of SAKK came as a big and painful surprise. Together with the SAKK Coordinating Center, we are now trying to assess the impacts on our activities. This includes the data collection of our own trials with completed accrual (SAKK 39/16, SAKK 36/13, SAKK 35/14) regarding speed, extent, and completeness, which will have a major effect on the quality of the resulting publications. Also, we want to avoid any negative effects on our longstanding collaborations with other groups, such as the International Extranodal Lymphoma Study Group (IELSG), German Hodgkin Study Group (GHSG), the Haemato Oncology Foundation for Adults in the Netherlands (HOVON), and the European MCL Network. In addition, the measures

caught our group on the wrong foot and in a vulnerable phase, as we were well on the way to finally launch trials for patients with diffuse large B-cell lymphoma (**SAKK 38/19 PEDRO**) and Hodgkin's disease (**RADAR**), two of the three most frequent lymphoma entities.

We therefore called for new and active participation of the group to channel available internal funds that had been reserved for clinical research for non-Hodgkin lymphomas. As much as we would like to continue academic clinical cancer research in this existing national network, we must have the courage for a thorough and critical analysis so that needed structural changes in SAKK can be undertaken. Only this will ensure a new and sustained perspective for future academic clinical cancer research that is attractive enough for all stakeholders, including our young colleagues.

Project Group Urogenital Tumors

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

2020 was another successful research year for the SAKK Project Group Urogenital Tumors (PG URO), with high recruitment rates. A total of 388 patients were recruited into 11 open trials in 2020, 49 of them into the SAKK 63/12 biobank trial, 77 patients in SCORED registries (SAKK 80/19 AlpineTIR and SAKK 80/20 CaSA), and the others into classic interventional drug trials.

The 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 results were submitted for a presentation at the ASCO GU 2021 Genitourinary Cancers Symposium. A follow-on project is being planned and can hopefully be opened in 2021.

Trial **SAKK 01/18** for germ cell tumors was opened in 2019 as a follow-on project to the SAKK 01/10 trial. 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. 20 patients had been recruited by the end of 2020.

Trial **SAKK 07/17** for renal cell carcinoma was also 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 37 patients. 35 patients are currently enrolled in the expansion cohort.

Prostate cancer remains the group's primary focus, with a total of six 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), were published successfully in 2020 in a paper co-authored by members of the SAKK PG URO.

SAKK 09/18 trial has been running since 2019, recruiting patients with localized prostate cancer (intermediate or high-risk) and randomizing them to pelvic lymphadenectomy or not. 57 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.

SAKK 08/16 (maintenance therapy with enzalutamide or placebo after chemotherapy with taxanes) was successfully concluded, and the results will be presented at one of the forthcoming conferences.

SAKK 08/14, a trial investigating the effect of metformin in the hormone-sensitive and castration-resistant context, is also on the home strait. The final patients are expected to be recruited in the first quarter of 2021.

SAKK 08/15 (salvage radiotherapy with increased PSA after local therapy plus/minus metformin) recruited further patients in 2020, mainly with the assistance of sites abroad, and now has 111 of the 170 required patients.

For the **SAKK 96/12** trial (denosumab every 4 weeks versus every 12 weeks in prostate cancer and breast cancer), 1,178 of the planned 1,380 patients were recruited.

The 2nd SAKK Translational Prostate Cancer Young Scientist Meeting was renamed SAKK Translational Urogenital Cancer Network Meeting & Award; it had to be postponed from September 2020 to October 2021 because of COVID-19. The aim of this initiative is to better network people working in basic and translational urogenital research with those active in clinical research, and to develop ideas for potential SAKK trials or translational projects associated with planned or ongoing PG URO trials. In addition, a prize for translational research will be awarded at the 2021 meeting.

Working Group Cellular Therapies

President: Prof. Dr. med. Dr. phil. George Coukos,
Lausanne University Hospital (CHUV)
Vice presidents: Dr. med. Francesco Ceppi,
Lausanne University Hospital (CHUV)
PD Dr. med. Heinz Läubli, University Hospital Basel
PD Dr. med. Antonia Maria Müller, University Hospital Zurich
Prof. Dr. med. Dr. phil. Sacha Zeerleder,
Inselspital Bern (University Hospital of Bern)

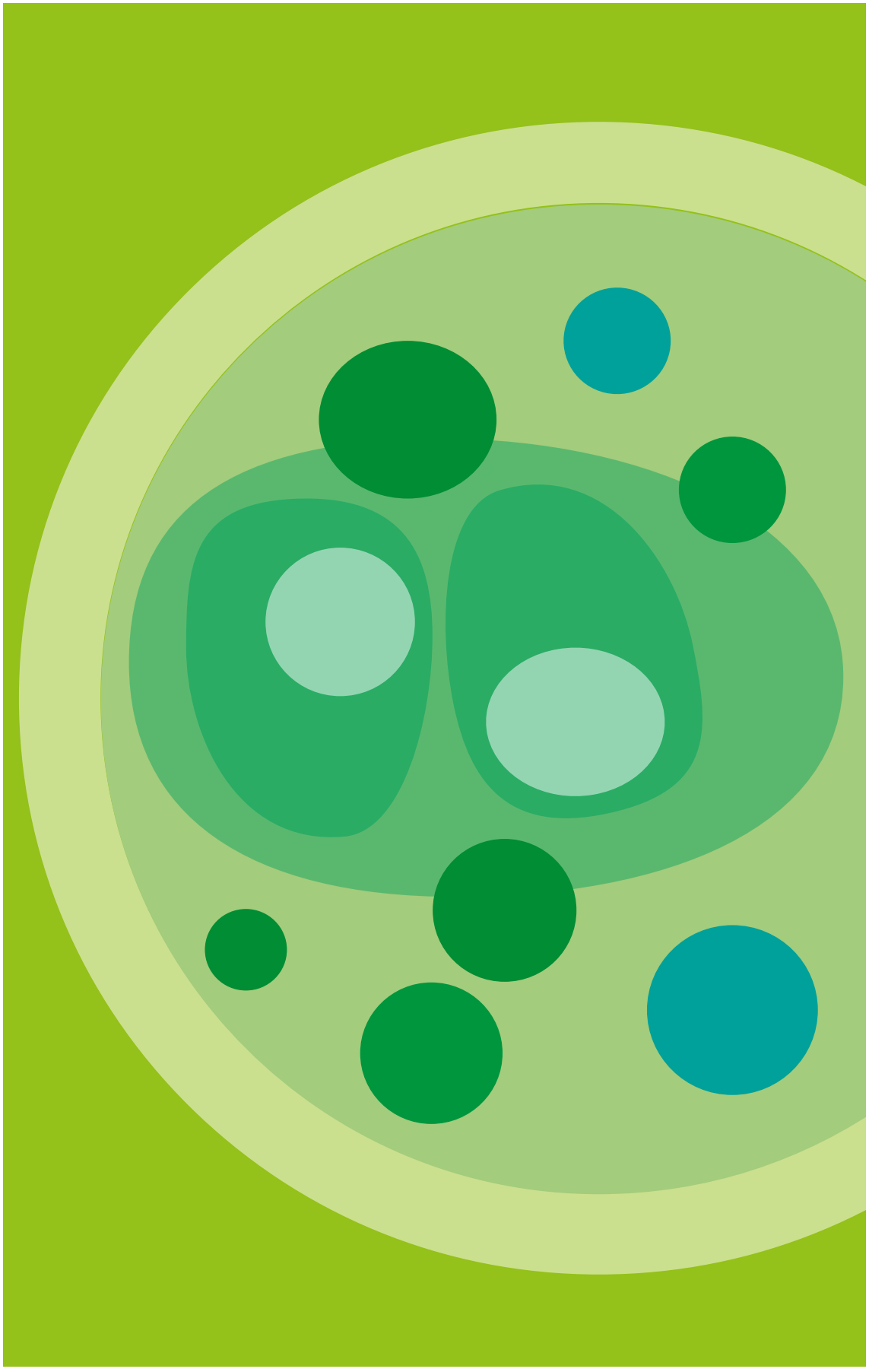
Launched in November 2019, the Working Group Cellular Therapies was fully operational throughout 2020. The core team of the group, consisting of the president, George Coukos, and the vice presidents, Antonia Müller, Heinz Läubli, Sacha Zeerleder, and Francesco Ceppi (representing the pediatric oncologists), are supported and complemented by Caroline Arber (representing the Swiss Blood Stem Cells Transplantation, SBST).

The core team met approximately on a monthly basis and worked together enthusiastically to move cell-based technologies in Switzerland rapidly forward and to develop a framework of goals, processes, and milestones. The group felt regular and frequent conversations were necessary to get to know each other well and to develop an 'identity' for this new working group.

The members of the entire working group comprise 88 members from 20 sites; they met four times in 2020. In addition to exchange of information and lively discussions, interesting translational research projects were presented and evaluated. Based on the fruitful discussions, some of these projects are advancing fast. The group established an overview of the Swiss clinical research landscape in development – both investigator-initiated trials and pharmaceutical industry-sponsored trials. The comprehensive list of investigator-initiated trials is shared within the working group to nurture collaborations and make these trials accessible to patients once recruiting.

The highlight of the year was the approval of the first pilot trial, **NeoTIL-ACT** (multicentered pilot trial to assess the feasibility, safety, and efficacy of adoptive transfer of autologous tumor infiltrating lymphocytes enriched for tumor antigen specificity in advanced solid tumors) by the working group and the SAKK Board. As cellular therapies are very expensive, a funding strategy was developed based on grants and partners, including the Swiss Cancer Research foundation, which is supporting us in our efforts to establish a Swiss network for cellular therapies.

As the regulatory hurdles for T-cell therapies are exceedingly high and change rapidly, we proactively sought dialogue with the responsible authorities, the Federal Office of Public Health and Swissmedic, to enable the best possible solutions for the Swiss platform for cellular therapies. Despite some hur-



dles due to the COVID-19 pandemic, the discussions and exchange meetings with both authorities were very constructive for moving this field of research forward and providing these highly effective and promising investigational therapies to patients in Switzerland.

Another topic that was discussed intensively during this first year was the aim to develop a mutual biobanking and data collection strategy as a critical basis for future non-interventional studies. These efforts are largely streamlined and will be implemented in the near future.

2021 will be a very decisive year for the Working Group Cellular Therapies. The aim is to open the first clinical trial in the Swiss network and to jointly implement the first translational research projects. The main hurdles to advancing these innovative cellular therapies will remain the same, specifically finances and regulatory hurdles. We are convinced that together, we will be able to surmount these obstacles and ultimately improve cancer care for all of our patients.

Working Group CNS Tumors

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

Neuro-oncology is a highly specialized field involving various disciplines, and tumors in the central nervous system (CNS) remain a particular therapeutic challenge. The major aim of the Working Group CNS Tumors is to strengthen the neuro-oncological community in order to provide brain tumor patients in Switzerland access to the best possible treatment options, including novel therapeutic concepts, which are tested in clinical trials.

In 2020, several members of the working group developed a consensus manuscript on the management of adult patients with diffuse gliomas in Switzerland. The article, published in *Swiss Medical Weekly,* summarizes key recommendations on the diagnosis, treatment, and follow-up of these patients and may provide a helpful guideline for many colleagues in Switzerland and beyond (available at https://smw.ch/article/doi/smw.2020.20256).

The group was able to include a total of 9 patients in the SCORED registry (SAKK 80/20 CaSA). Although CNS tumors have not been a scientific focus within SAKK for the last decades, the members of the working group continue to be very active on a national and international level. At several Swiss sites, clinical trials for brain tumor patients were available in 2020. As with other areas of clinical oncology, enrollment of patients into these trials was partially hindered due to the COVID-19 pandemic. Nevertheless, Swiss patients with brain cancer had access to various clinical trials. Some of these trials were exclusively available in Switzerland, thereby providing Swiss patients access to novel treatment options. Furthermore, there are ongoing efforts to develop new trial protocols and initiatives, with the hope that they can be realized within the SAKK network in the next years.

Working Group Gynecological Cancer

President: Prof. Dr. med. Viola Heinzelmann-Schwarz,
University Hospital Basel

In 2020 we continued successful recruitment into our three open ENGOT trials, namely, the ENGOT-en7_AtTEnd, ENGOT-ov50_INNOVATE-3, and ENGOT-ov40/Expression VI trial. The SCORED registries (SAKK 80/19 AlpineTIR and SAKK 80/20 CaSA) also enrolled patients, accounting for 44 % of all patients recruited in this group.

ENGOT-en7_AtTEnd is a trial examining the benefit of adding a checkpoint inhibitor to standard endometrial cancer adjuvant treatment. Endometrial cancer patients of advanced FIGO stage III/IV with residual disease or recurrent disease receive standard adjuvant chemotherapy with paclitaxel (175 mg/m^2) and carboplatin (AUC5 or 6) and placebo followed by maintenance placebo versus paclitaxel, carboplatin, and atezolizumab 1200 mg for

6–8 cycles or PD (progression of disease), followed by atezolizumab maintenance 1200 mg. Accrual of the trial has been slow in Switzerland and internationally. In 2019 and 2020, 19 patients were recruited, which is behind the expected accrual, partly because some sites could not begin recruitment due to unanticipated internal political difficulties. Due to the missing full cost coverage of this trial and also due to the slow recruitment, the SAKK Board unfortunately decided to close this trial.

ENGOT-ov50_INNOVATE-3 is evaluating the effectiveness of tumor treating fields (TT fields) in addition to weekly paclitaxel chemotherapy in patients with platinum resistant ovarian cancer with maximal two lines of chemotherapy after initial platinum resistance. This trial has full cost coverage, so will be able to go ahead. Recruitment is open at four Swiss sites only, namely, Bellinzona, Frauenfeld, Zurich (University Hospital), and Basel (University Hospital). With 13 patients enrolled so far, we are the eighth-best recruiting country in this trial. The target number for this trial is 540 patients.

Election of new vice presidents

At the end of 2020, we elected our new vice presidents: PD Dr. med. Intidhar Labidi-Galy (Geneva University Hospitals, HUG), Dr. med. Ursula Hasler-Strub (Cantonal Hospital St.Gallen, Breast Center), Dr. med. Apostolos Sarivalasis (Lausanne University Hospital, CHUV) and Dr. med. Ilaria Colombo (Oncology Institute of Southern Switzerland, IOSI).

Memorandum of Understanding (MoU) with the Swiss GO Trial Group

SAKK and the Swiss GO Trial Group have defined our collaboration with the help of an MoU. The MoU describes how the two organizations benefit from close collaboration, enabling the sites in Switzerland to enroll more patients in trials.

Running via Swiss GO Trial Group are the following two studies, for which the Working Group Gynecological Cancer (WG GYNE) is recruiting:

ENGOT-ov40/NOGGO/Expression VI is investigating the outcome of long-term ovarian cancer survivors 8 years after their diagnosis. Switzerland has so far contributed 117 patients to the trial, making us the third-best recruiting country. A poster at ASCO 2020 by Woopen et al. presented P. Samartzis and V. Heinzelmann-Schwarz's first results on fatigue from this trial.

A major highlight of this year was the opening of our own first Swiss-initiated and Swiss-led ENGOT trial. This has been a particular success and milestone in the group's history. **ENGOT-54/Swiss-GO/MATAO** is examining endocrine treatment with Letrozole in the maintenance of newly diagnosed FIGO stage III/IV epithelial ovarian cancer that under adjuvant standard chemotherapy has not progressed. Additional treatment with PARP inhibitors or Bevacizumab is allowed. By the end of 2020, our first 12 patients were enrolled in this trial. For the trial, we have opened 20 Swiss sites and have a target accrual volume of 540 patients. A distinguishing feature of the trial is also that have established a national center for centralized pathological review, which also performs immunohistochemical testing for ER. Quality of life will be analyzed in this trial for the first time ever using a digital app as well as a vital signs armband providing information on the patient's pulse, oxygenation, blood pressure, temperature, and activity.

Working Group Head and Neck Cancer

President: PD Dr. med. Marco Siano,
Seeland Cancer Center Biel
Vice president: Prof. Dr. med. Christian Simon,
Lausanne University Hospital (CHUV)

In this difficult year, the MaxiVAX trial (SAKK 11/16) and the 'best of' SAKK 10/16 trial were open and recruited patients. A proposed follow-up trial received support from the management, and we are in the process of identifying funding in line with the new requirements.

The **SAKK 11/16** trial is investigating whether immunotherapy with MVX-ONCO-1 is effective, safe, and well tolerated in patients with advanced head and neck squamous cell carcinoma. This immunotherapy consists in 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 sites. As the first interim results are looking good, the number of patients that need to be recruited can be reduced slightly, and we now expect to be able to recruit the minimum number of patients despite the difficult circumstances.

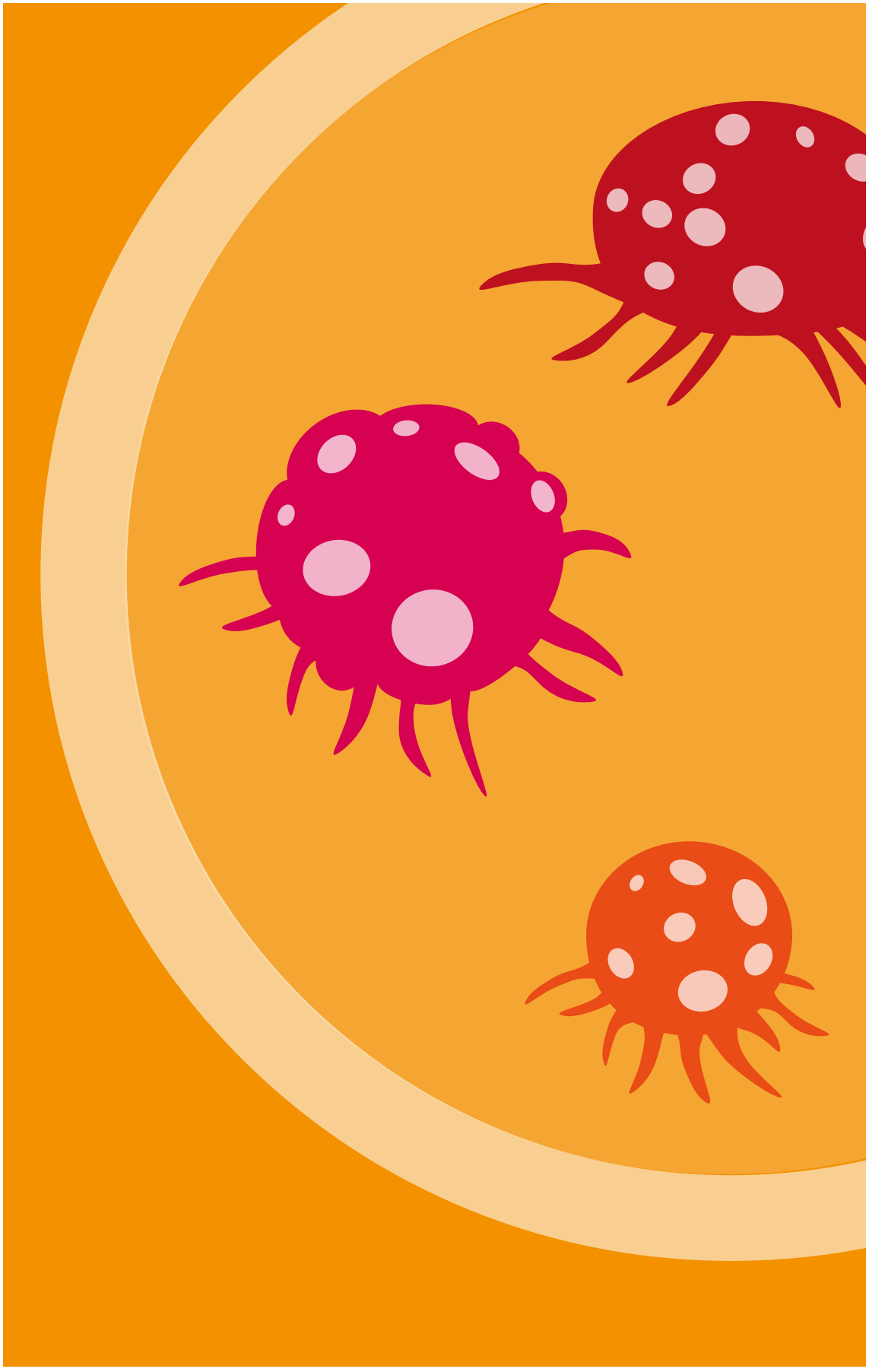
The 'best of' **SAKK 10/16** trial is recruiting the required patients in Switzerland, and Lausanne in particular; recruitment in the rest of Europe gained momentum at the end of the year. Going forward, the trial will be sponsored directly through EORTC, enabling it to be continued as before. It remains 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.
In addition, patients could be included in the two SCORED registries (SAKK 80/19 AlpineTIR and SAKK 80/20 CaSA).

Working Group Imaging in Diagnostic and Therapy Monitoring

President: Prof. Dr. med. Lukas Ebner,
Inselspital Bern (University Hospital of Bern)
Vice President: PD Dr. med. Andreas Hötker,
University Hospital Zurich

The Working Group Imaging in Diagnostic and Therapy Monitoring (WG IDTM) is made up of members from the fields of radiology, neuroradiology, and nuclear medicine along with interested individuals from oncology and radiation oncology, thus forming an interdisciplinary network of clinicians and researchers dedicated to improving diagnostic imaging as well as prediction and assessment of therapeutic response in oncology patients. Imaging is an integral part of nearly all clinical trials in oncology and acts as a means for reliable diagnosis, but even more importantly it represents the most used method to assess the response of a tumor to treatment. Although this can be achieved with standard CT (computed tomography scan), PET (positron emission tomography), or MRI (magnetic resonance imaging) examinations, newer technologies in these fields offer a more in-depth insight into tumor microbiology and tissue characteristics not quantifiable by standard clinical imaging studies. The aims of the working group are therefore not only to provide a network of experienced and certified physicians for trials (i.e., to allow for a centralized imaging review) but also to further advance knowledge in the context of research projects dedicated to investigating novel techniques for tumor response assessment.

Given the COVID-19 pandemic in 2020, all group meetings were held as virtual meetings, the last one in November 2020. At this meeting PD Dr. Thi Dan Linh Nguyen-Kim at University Hospital Zurich presented a study approach for applying these research aims to bladder cancer treated with novel neoadjuvant chemotherapy, possibly allowing for faster and more precise response assessment.



Also, Prof. Andreas Christe at Inselspital Bern shared his approved study investigating therapy response by means of volumetric assessment and RECIST criteria in advanced stage lung cancer. This retrospective trial includes patients in the SAKK 19/05 and SAKK 19/09 registries. The primary objective is to compare the accuracy of prediction of overall survival after two cycles of chemotherapy between classifications based on computer-aided volumetric analysis and based on diameter measurement applying the RECIST criteria.

In 2021, the WG IDTM will focus on expanding and gaining new members from all fields of imaging, being available for advising when new investigative trials are designed, and further improving imaging techniques to perform response assessment in oncology by developing and conducting research projects.

Working Group Melanoma

President: Dr. med. Johanna Mangana,
Zurich University Hospital
Vice president: Dr. med. Yannis Metaxas,
Cantonal Hospital Graubünden

Due to the major achievements and several approved therapeutic regimens in recent years in the melanoma field, initiation of national phase I-II trials is becoming challenging. At the previous SAKK semi-annual meeting in May, the scientific committee approved the initiation and conduction of **SAKK 50/20** "Chemo-immunotherapy with carboplatin-paclitaxel, bevacizumab and atezolizumab in LDH-high melanomas: a phase II trial with a safety run-in" (80 % covered by Roche). However, and due to the current financial restructuring plan of SAKK, the development of the trial was put on hold.

The group was able to include a total of 32 patients in the SCORED registries (SAKK 80/19 AlpineTIR and SAKK 80/20 CaSA).

Scientific projects including the CTLA-4 SNP project are ongoing; results are expected in Q3 2021.

Outlook

- Few sites in Switzerland perform active melanoma research. Widespread clinical activity is challenging in the time of the COVID-19 pandemic, but we hope to improve as the pandemic gets under control.
- Update of Swiss Melanoma Guidelines to be actively discussed in 2021.

Working Group Sarcoma

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

On the whole, 2020 was a successful year for our research group, despite the obstacles raised by the COVID-19 pandemic. The level of motivation and dedication among our members in promoting clinical sarcoma research at the national level remains high. In 2020, patients in Switzerland were able to take part in two clinical sarcoma trials. Intensive efforts were also made to open new trials.

- The highlight of the year was the rapid recruitment of patients into the phase I/II **SAKK 57/16 (NAPAGE)** trial, which was completed at the end of the year. This partial completion reflects the successful collaboration between the sarcoma sites and at the same time underlines the need for innovative clinical sarcoma trials in Switzerland. Some 39 patients in total took part in this trial. The analysis of the primary endpoint is expected in the coming months.

– The **PazoQoL or GISG 11** trial, on the other hand, had to be discontinued prematurely owing to insufficient recruitment in Germany and Switzerland. In this multicenter phase III trial, which compares palliative systemic therapy in the form of pazopanib with a freely chosen palliative chemotherapy, patients' quality of life was to be studied using patient-reported outcomes.
– **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. SAKK was in regular contact with EORTC to negotiate contracts. Unfortunately, it will not be possible to open this trial in Switzerland for the time being due to the current restructuring of SAKK and the lack of viable funding.
– Once it became known that the primary endpoint had been reached in the interim analysis of SAKK 57/16, the idea of taking it as the starting point for a trial with the title "Nab-paclitaxel, gemcitabine and nivolumab in advanced soft tissue sarcoma, a multicenter open-label single arm phase Ia/II trial" (**I-NAPAGE**) was discussed. This idea is hanging in the balance in the absence of interest from the pharmaceutical industry.
– **FaR-RMS trial**: Our Working Group focused on the opening of this academic, international, multicenter trial to optimize treatment of rhabdomyosarcoma patients. Cooperation with the Swiss Paediatric Oncology Group (SPOG) was evaluated. This trial cannot be opened at the moment due to lack of funding.

Dr. med. Niels Junker, an oncologist in Denmark and an active member of the EORTC Soft Tissue and Bone Sarcoma Group whose main research interests are sarcoma and immunotherapy, summarized the role of immunotherapy for sarcomas in a virtual presentation designed to promote international exchange and stimulate discussion.

Sarcomas are rare and heterogeneous tumors. The financial obstacles associated with academic trials in this field and the need to promote an industry focus on this rare tumor entity represent major challenges for our group.
The group was able to recruit 33 % of its total patient population into the SCORED registries (SAKK 80/19 AlpineTIR and SAKK 80/20 CaSA).

Working Group Supportive Care & 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), Bern
Prof. Dr. med. Claudia Witt, University Hospital Zurich

The research interests of the Working Group Supportive Care and Palliative Cancer Care cover a wide range of topics related to supportive and palliative care interventions, geriatric oncology, psycho-oncology, and cancer rehabilitation. In 2020, several proposals were discussed, two of which were submitted to the SAKK Board. The first trial aims to assess the **prevalence of functional iron deficiency** in patients with oncological and hematological malignancies at five large cancer SAKK sites. The second, a qualitative trial, aims to describe **patient reported experiences of cancer care related to the COVID-19 pandemic** in Switzerland.

This trial was approved by the SAKK Board in August 2020. Due to the financial restructuring of SAKK, it will be conducted on a smaller scale without further SAKK support. Other trials in preparation include:

- the **signal light trial**, which aims to investigate different methods of objective prognostication before tumor-directed palliative treatment
- a pilot trial **evaluating decisional conflict and regret in clinical cancer trials**, which aims to systematically investigate outcomes related to decision-making processes of patients eligible for four selected SAKK trials with a focus on decisional conflict, decisional regret, quality of informed consent. and decision-making involvement and satisfaction
- **Swiss Cancer Patient Experiences-2 (SCAPE-2)**, a trial that aims to assess patients' view of the delivery of care with patient-reported experience measures (PREMs). Pending on funding, this trial may be conducted within the SAKK network.
- a trial addressing **advanced care planning**, which aims to show the benefit of a pragmatic advance care planning (ACP) intervention led by oncologists on patient unmet palliative care needs using the SENS structure and to assess the effect of the intervention on quality of life and distress

The results of the analysis of secondary outcomes (patient-reported outcomes) from **SAKK 95/16**, a cross-sectional trial describing patterns of care in Switzerland for patients with metastatic bone disease in solid tumors, were presented as a poster at ESMO 2020 and SOHC 2020. The corresponding manuscript was submitted to *BMC Cancer* in November 2020.

Finally, several members of the working group are significantly involved in the development of an overall SAKK strategy for the assessment of electronic patient-reported outcomes (ePROs) and have been designated to establish a minimal ePRO data set for the Real World Data (SCORED) project.

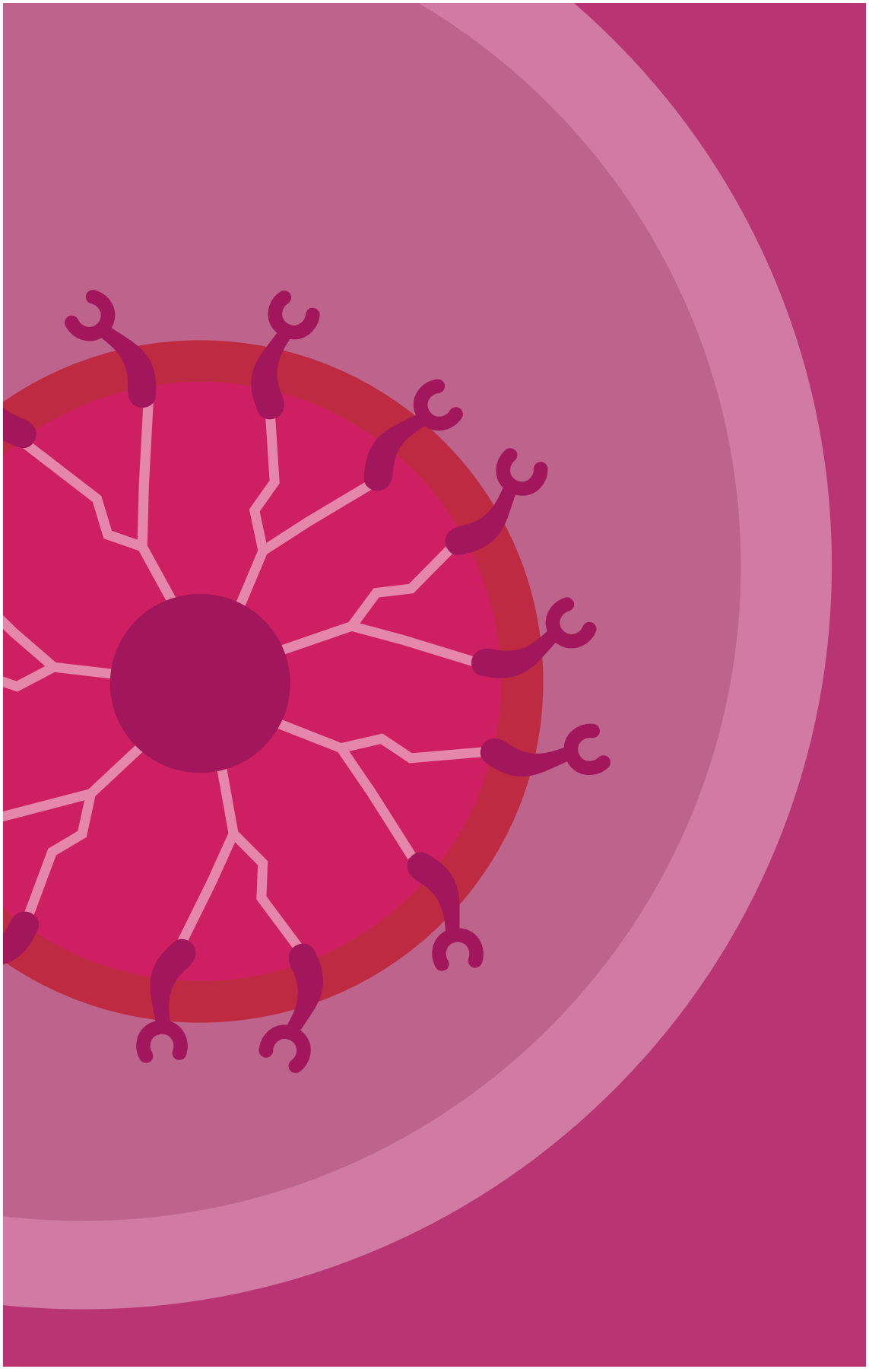
Section Network for Cancer Predisposition Testing and Counseling

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

In 2020, despite all the inconveniences of the COVID-19 pandemic, the Network for Cancer Predisposition Testing and Counseling (CPTC) remained active, and several projects came to fruition. The annual course on Genetic Counseling in Oncology took place in February and was one of the last pre-lockdown in-person events. It was again a success, with many of the students going on to become CPTC members. It is planned again for 2021 in two versions: one in St.Gallen and, for the first time, one in Lausanne for French-speaking collaborators.

The guide for genetic counseling for hereditary breast and ovarian cancer (HBOC) developed by the CPTC Network proved to be such a success that the group has developed a guide for Lynch syndrome. This project was done by Dr. med. Susanna Stoll and the vice president of the CPTC Network, Dr. med. Salome Riniker. The Lynch syndrome guide is now available and can be downloaded from the SAKK website; a printed version is available from the Swiss Cancer League.

A long-term project was accomplished: The Federal Office of Public Health approved the revised guidelines for breast cancer screening in women at increased risk. This project was led by PD Dr. med. Cornelia Leo and the president of the CPTC, PD Dr. med. Sheila Unger. It was a collaboration between the CPTC and the Swiss societies of senology, genetics, and gynecology. It will come into effect at end of January 2021 and represents a true win for our patients at increased risk of breast cancer, and it is an indication that personalized cancer prevention can work in Switzerland.



Our annual educational session was once again a success. As the SAKK semi-annual meeting was completely virtual, we were able to invite Prof. Steven Narod, a world expert on hereditary breast and ovarian cancer (HBOC), to address us from Toronto.

The CPTC network will continue to work on various projects in 2021, including revising the Swiss test guidelines for HBOC, which have now been approved by the CPTC members and have been submitted for publication, as well as following up the revision of Article 12d letters d and f of chapter 3 of the Health Insurance Benefits Ordinance (*Krankenpflege-Leistungsverordnung*, KLV).

Section Pathology

President: Prof. Dr. med. Rupert Langer,
Johannes Kepler University Linz (formerly at the University of Bern)

The Section Pathology functions as a diagnostic and scientific platform that offers support particularly for questions in the area of translational research and in connection with clinical trials.

It also deals with quality assurance in clinical trials regarding pathology diagnoses and with compliance with pre-analytical and analytical standards in tissue-based analysis. It sets standards for the application and introduction of new analytical methods. An ultimate goal is the quality and maintenance of archival tissue and living cell biobanks. At the same time, it initiates and runs its own projects in close collaboration with the SAKK project and working groups on specific cancers. 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). Pathologist Prof. Rupert Langer, previously at the University of Bern and now director of Pathology and Molecular Pathology at Johannes Kepler University Linz and Kepler University Hospital, implemented 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 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
Co-Author: SAKK Board Member Dr. med. Thomas Zilli,
Geneva University Hospitals (HUG)

Focusing on trials with high precision radiation application and complex treatment planning

In 2020, the section focused on improving quality assurance processes in future clinical trials and the integration of stereotactic techniques in multidisciplinary treatments. In locally advanced but resectable stage III(N2) non-small cell lung cancer (NSCLC), an immune-modulatory stereotactic and image-guided radiotherapy focused on the primary tumor is aiming to enhance the effects of neoadjuvant PD-L1 blockade and neoadjuvant chemotherapy in patients with stage III(N2) non-small cell lung cancer (NSCLC) within a multicenter single-arm phase II trial.

The patient recruitment in node-positive breast cancer (**SAKK 23/16 TAXIS**) was increased in close collaboration with the breast cancer surgeons and within a large European network of cancer centers and has now achieved the estimated accrual numbers. This is the largest trial of SAKK with active participation of radiation oncologists, and it will answer the question concerning compensation of restrictive axillary surgery by precisely planned dynamic intensity modulated radiation therapy (IMRT/VMAT) of the regional lymph nodes. In addition to the successful recruitment, the quality assurance group of the Section Radio-Oncology was able to gather additional information about treatment planning procedures in complex target volumes and the optimization of QA processes, which will be useful for future clinical trials of SAKK in solid cancers.

At the end of 2020, a new challenge and task for the section became evident: to manage the accrual of patients within the national network of radiation oncologists after the premature or interim closure of slowly accruing trials or in close cooperation within European organizations. The section members are optimistic for 2021 and will continue to conduct studies to evaluate the value of hypofractionated, image-guided, and stereotactic treatments in solid and limited metastasized malignancies, improve the local symptom control, and/or to delay the tumor progression to allow an optimal efficacy of systemic antibody therapies or immunotherapies.

Impact of the COVID-19 Pandemic and Measures Implemented

As the first wave of the COVID-19 pandemic hit, SAKK rapidly deployed the measures necessary to cope with thew impact on patients and developed the following important documents for attending physicians, nursing staff, and the COVID-19 task forces at Swiss hospitals, collaborating in some instances with other specialist organizations.

- **"Guideline for management of SAKK clinical trials during the COVID-19 pandemic"**
- **"Important information for working with cancer patients during the COVID-19 pandem"**
  (in conjunction with Oncosuisse)
- **"Work ability of oncology patients in compliance with the ordinance of the Federal Council (COVID-19 Ordinance 2)"**
  (in conjunction with the Swiss Society of Medical Oncology SSMO and the Swiss Society of Hematology SSH)

Risk analysis of ongoing trials

In line with the recommendations and measures adopted by the Swiss government to control the COVID-19 pandemic, ongoing trials underwent a risk analysis to determine the need for a temporary suspension of patient recruitment:

- Risk exposure of the trial population (age, performance status = 2, frequent visits, etc.)
- Specific vulnerability of the trial population
- Evaluation of potential benefit/risks
- Evaluation of increased risk compared with standard treatment

On the basis of this risk analysis, recruitment of patients into 16 of 55 ongoing trials was temporarily halted from April 1, 2020 and restarted on April 27. The temporary closure had no negative effects on patients who had already been recruited. As a result of suspended recruitment, the number of patients in SAKK clinical trials in April 2020 almost halved (from 114 in March to 60 in April), although this figure almost normalized again in May.

Financial repercussions

The suspension of some trials resulted in the patient fees paid to the recruiting sites not being remitted and in a reduction of the trial monitoring workload. At the same time, however, greater effort was required for risk evaluation and the associated necessary communication with and coordination of researchers, study nurses, and research coordinators, which more than outweighed the savings. Against this background, no application for short-time working was submitted following analysis of the situation.

Trial SAKK 80/20: Outcome and prognosis for cancer patients with a coronavirus infection

The SAKK SCORED (Swiss Centralized Oncology Real World Evidence Data) project enabled the extremely rapid initiation of a new research project on the subject of cancer and COVID-19: SAKK 80/20 – "Outcome and prognostic factors of SARS-CoV-2 infection in cancer patients: A cross-sectional study." The first patient was recruited on April 17, 2020. This rapid activation of the trial was only possible because it was able to draw on the procedures and structures that had already been defined for the SAKK SCORED project. Twenty-three Swiss hospitals took part in this research project, which aims to generate evidence for treatment guidelines. By December 2020, 500 patients had been recruited and the first analyses had been completed. An abstract was submitted to the ESMO Congress and selected for an oral presentation. Important initial findings were generated from the treatment of cancer patients who were also infected with COVID-19; this is very relevant in view of the renewed increase in case numbers.

SAKK postgraduate training events
SAKK had to rapidly adapt its planned postgraduate training events to virtual and hybrid formats in order to safeguard knowledge transfer and the exchange between researchers despite the difficult conditions during the COVID-19 pandemic. Despite the major challenges (very little time for preparation, frequently changing official requirements), the SAKK event management team succeeded in implementing nearly all planned events.

The following events were adapted to the new format:

Chicago in the (cloudy) Mountains 2020: Switching to a hybrid format made it possible for the most important content from the scientific program of the Annual Meeting of the American Society of Clinical Oncology (ASCO) to be presented and discussed.

The **14th Swiss PostASCO** was postponed until August and was then successfully held in conformity with the COVID safety guidelines with some 100 participants at the Stade de Suisse soccer stadium. The **SAKK Training Course for CRCs and CTNs** was held on site in September 2020 with 20 participants. The **Swiss Hematology Workshop** was a fully virtual event broadcast via Zoom.

Thanks to the initiative of the established Chicago in the Mountains Meeting Steering Committee, it was possible to quickly organize a parallel meeting tying in with the ESMO Virtual Congress 2020; the **1st ESMO in the Alps** presented selected highlights to an audience of 120, who took part in the hybrid format either live or virtually.

The presentations at the **1st Swiss Post ESMO by SAKK Young Oncology Academy** were recorded and subsequently made available online. The fall Investigators' Education was an entirely virtual event. The **SAKK November 2020 semi-annual meeting** was held entirely virtually as part of the SOHC (Swiss Oncology & Hematology Congress), and the **patient forum** "Diagnosed with prostate cancer: The latest research findings for patients" also took place virtually.

In December 2020, SAKK organized the **1st Swiss SMASH** (**S**AKK **M**eets the hemato-oncological abstracts of **ASH**) event to view and discuss selected abstract presentations from the ASH annual meeting with nationally renowned experts. As a hybrid event, SAKK SMASH is likely to become a popular postgraduate training event for both specialists and doctors in office practice in the coming years.

We are confident that virtual events are set to become a permanent feature of the event landscape, as they offer so many advantages (less expense/time involved, lower environmental impact). However, attended events will continue to be important. Even though interactive formats allow a lively exchange to take place between participants in virtual meetings, we are convinced that they will never be able to emulate the advantages of a personal exchange entirely. We are therefore keenly looking forward to the time when we can organize at least some of our training and network events as physical events and are already looking forward to seeing you there!

Sandra Gadient
Patient Advisory Board
Program Manager/
Clinical Project Manager

SAKK Patient Advisory Board

SAKK set up the Patient Advisory Board in November 2015 with the aim to gain a better understanding of the experiences and needs of cancer patients and their families and use this information to inform SAKK research projects.

In 2020, the Patient Advisory Board supported nine trials by developing information for patients and making valuable suggestions for improvement. The Patient Advisory Board also made suggestions for modifying the patient information forms produced by Swissethics. Swissethics incorporated some of the suggestions in the revised forms published in December 2020.

We are very pleased to announce that two new members joined the Patient Advisory Board in 2020, now enabling patient information to be checked in French and Italian as well.

In the future, the input of the Patient Advisory Board will be increasingly taken into consideration at the planning and development stage of trials, so as to include the needs of patients in the study design.

Numerous ongoing projects were continued in 2020. The Patient Advisory Board again hosted a SAKK Patient Forum tying in with the SAKK semi-annual meeting in November 2020. This public event on the topic of prostate cancer was organized virtually for the first time due to COVID-19. Patients, their families, and interested individuals were able to watch videos on the topic and then put their questions to the experts during an online meeting.

In 2020, the Patient Advisory Board was also consulted to a greater extent by external partners (federal government, research institutes, healthcare organizations) and provided active support for various projects. Collaborations with institutions such as Unisanté, Lausanne University, and Swiss Clinical Trial Organization (SCTO) are ongoing.

One new and important project is summarizing the results of SAKK trials in language that is accessible to non-experts, with the aim of making findings available to trial participants and the public. In this context, cooperation with a number of organizations involved in clinical trials was intensified and a pilot project was launched for two SAKK trials.

The valuable support provided by the Rising Tide Foundation for Clinical Cancer Research will make it possible for the Patient Advisory Board to continue refining ongoing projects and implementing new ones in the coming year.

Interviews with SAKK Employees

In this special year, we would like to feature the people working at SAKK in our annual report. Members of 11 selected teams at the SAKK Coordinating Center (SAKK CC) in Bern responded to the following five questions:

- In what area of SAKK do you work?
- What motivated you to start working at SAKK, and what motivates you now?
- What do you like about SAKK?
- How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?
- What would be your wish for the future of SAKK?

Tanja Brauen, Marketing Assistant

In what area of SAKK do you work?

I'm a Marketing Assistant in the Fundraising & Communication team, which became part of the Services team in January 2021. My main tasks are the organization and implementation of internal and external events, postgraduate training events and the Young Oncology Academy.

What motivated you to start working at SAKK, and what motivates you now?

The organization of events for medical experts is a varied, fascinating, and challenging job. I like the fact that each event is unique and changes from year to year.

What do you like about SAKK?

I like the open, friendly, and transparent communication and our main objective of doing good for the Swiss population with a non-profit rather than a commercial approach.

How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?

I think the restructuring plan for SAKK is necessary. It doesn't impact my work directly, as I am not directly involved with trials. The biggest change is that the team to which I belonged until the end of 2020 was dissolved because employees who left were not replaced. The Marketing and Communication team has been part of the new Services department since the start of 2021.

What would be your wish for the future of SAKK?

I hope that the restructuring plan can be implemented as foreseen and SAKK will be back on a healthy footing soon.

Sabine Bucher, Politics & Development

In what area of SAKK do you work?

My job title is Politics & Development. Politics consists of observing relevant political developments and coordinating corresponding actions if necessary (consultations, opinions), and also cooperation with major stakeholders and authorities. The Development area comprises my responsibility for the international Scientific Advisory Board meeting, among other things, and I am involved in strategic developments.

What motivated you to start working at SAKK, and what motivates you now?

With training in psychology and previous employment in public health I was keen to get involved in the world of academic clinical research. I thought I could put my strengths to good use in this job – and that has turned out to be the case. As time went on, the value of this work took on increasing importance as I became aware of the challenging environment in which independent clinical research takes place.

What do you like about SAKK?
I find the way people at SAKK work together across departments and hierarchies to be very cooperative, professional, and supportive – in spite of sometimes stressful situations. The way work is organized is flexible and gives me a large degree of autonomy.

How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?
Along with the inevitable uncertainty, I'm now feeling rather defiant: 'Now more than ever'! The services that SAKK and the researchers at the member hospitals provide are important for patients and society – and it is worth rising to the challenge. On a personal level, I'll be reducing some of the specifically political tasks that I've been doing; instead, I'll be supporting the Fundraising section with reporting to foundations.

What would be your wish for the future of SAKK?
I very much hope that the loss of valuable employees will be kept to a minimum and that the planned and ongoing measures will ultimately lead SAKK into a stronger future.

Sandra Calmonte, Clinical Data Management

In what area of SAKK do you work?
I develop and produce the data acquisition concept for a trial. Among other things, this includes transferring the protocol into a database. I have to try and reconcile the needs of all the individual players (statistics, safety office, principal investigators, etc.). It's important for the concept to be as complete as possible by the time the trial starts, because subsequent modifications often mean a lot of work for the sites.

At the same time, though, changes are sometimes necessary, for example if new, relevant medical findings emerge. My task then is to incorporate this into the existing structure in such a way that data that have already been acquired retain their significance and the new requirements are covered at the same time.

What motivated you to start working at SAKK, and what motivates you now?
The main motivator for me at the time was that I no longer had to commute over an hour each way to work and back. The time I save is very valuable to me. It's also important to me that I can use my skills for something that (hopefully) benefits the world.

What do you like about SAKK?
I really enjoy working at SAKK. Here I'm able to make active use of my specialist knowledge to develop a trial. I can design complex databases, and that's a really fun thing to do. The working atmosphere is also pleasant and appreciative.

How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?
I'm hovering somewhere between curiosity and stress. On the one hand, it's interesting to see how SAKK got into this situation and what actions now have to be taken. That part is very instructive and fascinating.

At the same time, the uncertainty is stressful. Many aspects of my trials will be changing in the near future, but we don't know yet when and how these changes will happen. I don't get to look behind the scenes of the decision-making process in my position; I just receive information now and then. But at the same time, a trial-specific situation can change completely from one update to the next. At the moment I can only plan from one week to the next; that's pretty unusual for me, because my trial-specific planning is normally done months in advance.

What would be your wish for the future of SAKK?
That things settle down soon and we can concentrate on the trials again. Because cancer will continue to be an important topic in our society.

Andrea Fuhrer,
Clinical Project Management/Development

In what area of SAKK do you work?
I work in the Clinical Project Management department and am responsible for developing, planning, and coordinating specific clinical trials assigned to me. This task also involves liaison with the project groups in our network to develop ideas for new trials and coordination between the various players (investigators, Board, pharmaceutical companies, etc.).

What motivated you to start working at SAKK, and what motivates you now?
That was a long time ago ... I was looking for a route into clinical research and away from basic research in a laboratory. I applied for two different jobs at SAKK and was also thinking of doing a BNF internship if neither of them worked out. That shows how little idea I had of the business then, but it also shows that I like the SAKK ideology of working for patients without making a profit from it and want to be a part of that.

What do you like about SAKK?
Lots of things ... otherwise I wouldn't still be here 9 years later! My job at SAKK is incredibly varied. The interactions between the different departments at the SAKK CC and within our network bring new challenges every day. I've never been bored once at SAKK in those 9 years. I also find the spirit at SAKK great! For me, SAKK isn't just a group of colleagues; it's become a kind of family.

How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?
I'm sorry that this had to happen, and I'm also a bit shocked that nobody realized sooner what the situation was and that corrective action wasn't taken. But hindsight is 20/20 and always easier than foresight. The restructuring plan is essential for SAKK's survival. It is impacting everyone who works here. I'm especially sorry to see important and good employees lose their jobs.

What would be your wish for the future of SAKK?
That things calm down again soon. That we can look to the future again and not lose our spirit!

Isabel Gysi, IT Data Architect

In what area of SAKK do you work?
As a Data Architect my main task is to look after the data warehouse and the reports, and I try to establish new standards at SAKK in the form of data, processes, structures, or interfaces. My aim is to ensure that data are evaluable, reusable, and of good quality, and in this context, standards have the effect of reducing costs. In my first year at SAKK I produced models of our data, system, and interface landscape so that we can test the impact of future change requests or new system releases.

What motivated you to start working at SAKK, and what motivates you now?
I got to know SAKK as an external associate. What motivated me most to join SAKK was the worthwhile work being done by the organization and the respectful way everybody works together. The data warehouse and my curiosity about working in the health and research sector were additional driving factors.

Today I'm additionally motivated by working to promote the meaningful purpose of SAKK despite the difficult circumstances. The current system landscape is challenging, but that equally presents an opportunity for a redesign using enterprise architecture management. In addition to my day-to-day work, the IT projects, and the SCORED project in particular, are very interesting.

What do you like about SAKK?
SAKK is a social and progressive employer, one that promotes part-time working and gender equality and has understood that these can work to its advantage. What I like most are the company culture and the opportunity to work independently with all the departments and teams.

How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?
The restructuring plan is a premise for the future of SAKK. We have decided to take this approach to enable SAKK to continue to exist and be guided into a solid and sustainable future. That's why I'm supporting the restructuring plan. It affects the area I work in because this is being expanded. Necessary projects in our area will probably have to be postponed. We will have to focus and prioritize more intensively if we are to master this approach with limited financial resources.

What would be your wish for the future of SAKK?
I hope that the implementation of the restructuring plan creates a stable financial basis. The redesign of the IT architecture must be defined and implemented in line with the SAKK strategy so that IT can ensure sustainable cost-effectiveness and agility in meeting new internal and external requirements.

Niels Jensen, Accounting

In what area of SAKK do you work?
Accounting/Finance: preparing the annual accounts, auditing, the budget process, internal and external evaluations, entering all invoices (accounts payable & accounts receivable), payment of all invoices, system improvements such as the accounts payable process, reporting tool, debugging Abacus, etc. I also help look after trainees and provide other forms of internal support where necessary and possible.

What motivated you to start working at SAKK, and what motivates you now?
As an external consultant I was looking for a challenge, a job in which I could implement my ideas and suggestions for improvement. I found it at SAKK. This is still motivating me today, because I've still got more ideas, even after 2 years.

What do you like about SAKK?
I think it's good that SAKK is a not-for-profit organization in the research field. We have a modern structure and were able to transition to working from home, for example, without any major changes. I appreciate the opportunities I have for putting ideas into practice and the uncomplicated support I get from everyone who works here.

How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?
The steps that have been taken so far seem to be the right ones. But the knowledge and lessons learned from the discussions still need to prove that they are sustainable and can continue to be applied in the future. Apart from the additional time I still need for my work, my thoughts are with colleagues who have lost their jobs.

What would be your wish for the future of SAKK?
Stability, less employee fluctuation, being able to work together in the office.

Zuzanna Maniecka,
Clinical Project Management

In what area of SAKK do you work?
I'm a Clinical Project Manager. This means that I coordinate the conducting of clinical trials in compliance with the recognized ethical guidelines and requirements of Good Clinical Practice (ICH-GCP). I liaise, coordinate, and organize between the hos-

pitals, the SAKK trial team, pharmaceutical companies, and other external partners to make sure that the trials run smoothly.

What motivated you to start working at SAKK, and what motivates you now?

I did a PhD in neurodegenerative diseases in a laboratory at the University of Zurich, and then I wanted to move from research into a more practical setting where my work would help patients directly. What motivates me in my day-to-day work is the freedom and the enormous trust that SAKK places in each employee, which allows me to develop myself further.

What do you like about SAKK?

I really like the fact that SAKK is not profit-oriented and that patients always come first. We provide a platform for doctors and researchers, helping them to exchange ideas and knowledge so that patients can benefit from improved or new treatments.

How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?

It's very sad, of course, that so many colleagues have had to leave us. Things are also very difficult because we can no longer carry out a lot of trials, or we have to end them prematurely. But I think it's very positive that we are facing up to the problems, helping each other, and looking for solutions together.

What would be your wish for the future of SAKK?

I very much hope that we will have overcome our current problems 2–3 years from now and that we can get back to focusing fully on our core activities.

Miriam Paulisch, Regulatory Affairs

In what area of SAKK do you work?

I have a 60 % position in Regulatory Affairs. Our team submits trials to the Ethics Committees (EC) and to Swissmedic. This includes tasks like reporting changes to our ongoing trials, such as modifications of the protocol or trial design or treatment changes, the opening of additional sites, and changes relating to patient safety. We are basically the interface between the trial team and the authorities, and we make sure that this exchange operates correctly.

What motivated you to start working at SAKK, and what motivates you now?

Before coming to SAKK I was a trial coordinator at Inselspital Bern, so I was already involved in clinical research, albeit in neurology. But I've always been interested in oncology. I think this area of research particularly deserves to be promoted. Cancer concerns everybody. We all know someone who is affected by the disease. SAKK handles the full range of oncological trials, from rare sarcomas to breast cancer, which is very common. The size of the organization is right, too. As part of a medium-sized organization, you're not anonymous and there are enough people to talk to. I greatly appreciate the location near the railway station in Bern and the modern, flexible working conditions.

What motivates me today? I'm finding it a bit difficult at the moment. Our team has been cut almost in half; instead of five employees, there are now just three of us. When you're working from home you also tend to lose touch with colleagues outside your own team. In Regulatory Affairs we've had to notify the authorities of a large number of trial closures, and now we're trying to advance the trials that are ongoing or under development as well as we can. Despite the fact that, in most cases, patients in trials continue to be treated as they were

before, I still find trial closures and suspensions problematic. I very much hope that SAKK's financial situation will improve soon.

What do you like about SAKK?
I think it's good that everyone can be just the way they are here and can express their opinions freely. I also appreciate the opportunities for further training. If you're interested in something, you can pursue it even if it's not directly connected to the work you're doing. Another positive aspect is that you can usually organize your work flexibly. The working atmosphere at SAKK is basically very good; at the moment it's just suffering somewhat from the mass terminations and requirement to work from home.

How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?
I think it's a great pity that people had to lose their jobs. Unfortunately, I still don't really understand how such an enormous deficit could develop. I think that those responsible weren't properly held to account. The impact of the restructuring plan is definitely being felt. The terminations have meant that we have had to reorganize the team and distribute work differently. The additional tasks that I used to handle easily now unfortunately have to take second place until the day-to-day business is done.

What would be your wish for the future of SAKK?
I wish we could take on board financial experts who would make sure that financial problems like this never happened again. There are signs that things are moving in the right direction. I think it's good, for example, that we are now doing more reporting, and as a result we're getting the situation under control. The aim is to get the budget under control, get trials started again, and plan new trials in the future.

Thecla Pulvirenti, Safety Office

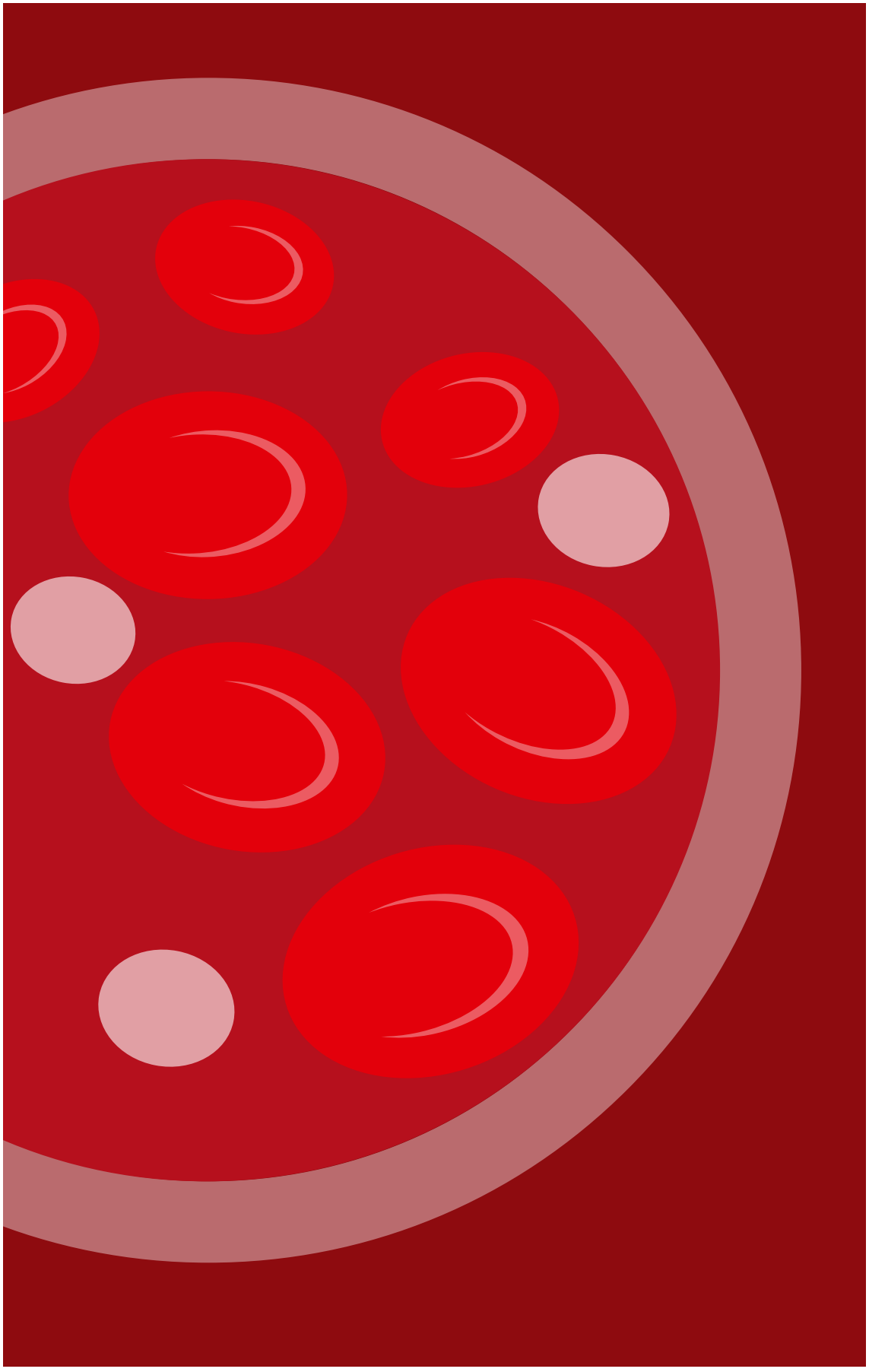
In what area of SAKK do you work?
My job title is Manager Safety Data. This mainly involves processing (documenting, reviewing, and correcting) incoming safety signals (SAEs) of patients in our clinical trials. Further tasks include preparation of safety reports such as Quarterly Safety Reports and Annual Safety Reports. I am also involved in the development of new processes within the Safety Office. Furthermore, I participate in the training of new employees and in the continuing education of the SAKK network colleagues such as CRCs (clinical research coordinators) and CTNs (clinical trial nurses).

What motivated you to start working at SAKK, and what motivates you now?
As I had previously worked at SAKK and supported its ethical values and field of work, I wanted to continue being part of it. Although I had another role then, my present position remains extremely interesting, challenging, and motivating.

What do you like about SAKK?
The flexible working arrangements allowing me to work part-time, thus managing both work and family life. I am part of a dream team of very competent and wonderful people. Not only are they supportive and committed but they also make my working time pleasant and fun!

How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?
It is very unfortunate that it had to come to such measures; however, it was necessary to allow the further existence of SAKK. I am deeply sorry for the ones who have lost their jobs.

What would be your wish for the future of SAKK?
A stable financial situation to allow SAKK to carry out its mission.



Lena Salzmann, Monitoring

In what area of SAKK do you work?

I am a Clinical Research Associate and I'm responsible for monitoring the trials assigned to me. I am the link between trial sites and the SAKK CC, and I'm responsible for quality control and compliance with Good Clinical Practice (GCP), regulatory requirements, and the trial protocols.

What motivated you to start working at SAKK, and what motivates you now?

After I'd completed my studies I wanted to continue working in a scientific environment. As a not-for-profit organization working in oncology research, SAKK offers the ideal combination of science and practical application in the clinical setting. The online presence and the job interviews additionally gave the impression of a very pleasant working atmosphere. This positive impression has been confirmed in the seven months that I've been working at SAKK. In addition to the valuable contribution to oncology research, I am motivated by the friendly and respectful way the employees behave towards each other, even though SAKK has been in pandemic mode for most of the time I've been here, including working from home.

What do you like about SAKK?

The good atmosphere among the employees. I felt at home and accepted right from the start. I also find the not-for-profit approach interesting – the focus is on the patient and not on commercial interests.

How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?

I also experienced a feeling of great uncertainty when the budget problems at SAKK were communicated. But we supported each other in the team. The thing that has affected me most so far is the potential closure of trials: It's not clear whether two of my trials will be continued. That introduces uncertainty and makes it difficult to plan monitoring. The feedback from the staff at the trial sites was also very varied, ranging from understanding for the situation at SAKK to frustration.

What would be your wish for the future of SAKK?

It would be great if funding could be found to continue some of the trials. A lot of resources have already been deployed, and this would show appreciation for people's efforts. I also hope that SAKK rapidly recovers from the impact of restructuring and will soon be able to go back to conducting clinical cancer research at the highest level.

Caroline Stepniewski, Statistics

In what area of SAKK do you work?
I work as a statistical programmer. It's a fascinating job because I can do a very wide variety of tasks in various areas and because I can work on a large number of different trials. These are some of the specific things I do: I program checks for the trials to review data consistency; I produce tables and graphs to illustrate study data for reports or publications or to visualize recruitment data at the end of the year; I write macros so that we can standardize and improve recurring tasks.

What motivated you to start working at SAKK, and what motivates you now?
When I started at SAKK I was very pleased to have found a worthwhile job. I felt that the work done by SAKK is a good thing and can help patients. Also, I've always been interested in research and think it's a fascinating job.

Today I still believe that what we are doing is worthwhile, and I find the programming tasks I do interesting and varied. In addition, I've learned a lot since I started working at SAKK.

What do you like about SAKK?
My work really fascinates me, and it's fun to work at SAKK. Above all, it's great working with my colleagues at SAKK. When we're not working from home because of COVID, our team spends all its breaks together and always has a fun time. I think it's great that we can have fun, too, and that I can work in the office with reindeer antlers on my head at Christmas.

How do you feel about the current financial restructuring plan at SAKK? Is it affecting you?
I think it's a great pity that some good colleagues have to leave us because of the restructuring measures. And, of course, the recent mood at work has not been as good as it used to be. I very much hope that the restructuring plan can be implemented effectively and that we will soon be able to work in a more relaxed atmosphere.

What would be your wish for the future of SAKK?
My wish is that SAKK will soon have a sound financial basis and that we can continue to make a contribution to the future development of cancer treatments.

Christine Biaggi Rudolf
Chief Operations Officer

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

Trial Activities and Quality Assurance

Very good trial and patient figures
Trial activities in the first three quarters of 2020 were again very gratifying. Despite the COVID-19 pandemic (which interrupted patient recruitment for one month in April) we were able to recruit more patients into clinical trials.

We recruited a total of 1,896 patients into the 58 open trials conducted by SAKK (including retrospective studies and registries), 1,699 of them from the Swiss member hospitals. This represented a significant increase in patient numbers compared with 2019 (1,335 patients).

The number of patients recruited into prospective clinical trials was down slightly this year with 1,186 patients compared to 1,211 patients enrolled in 2019. We did not quite achieve the goal that we had set for 2020 – to further increase the number of patients in prospective clinical. This was mainly due to the unexpected findings and resulting developments in Q4 2020.

Cooperation with Swissethics, the Ethics Committees, and Swissmedic
In 2020, the number of trials submitted to the authorities and approved and reports concerning our clinical research activities was comparable to the number in 2019.

The pandemic situation made it possible to submit documents to Swissmedic electronically by e-mail, which speeded up the process. Electronic submission to the Ethics Committees (EC) was implemented years ago in the form of BASEC; the pandemic had practically no impact here.

We held numerous constructive discussions with representatives of the EC and Swissethics and made progress with our SCORED project (real world data) and in managing hospital networks in clinical trials. The latter activity was also evaluated by Swissmedic, and we received valuable input on ways to further improve our concept.

	2019	2020
Total patients	**1335**	**1896**
Patients in Switzerland	1153	1699
Patients in other countries	182	197
Patients in SAKK trials	1079	1612
Patients in trials with other cooperative groups/partners	256	284
Patients in clinical trials	1211	1186
Patients in retrospective trials, cohort trials, and biobanks	124	710
Studies open for patient recruitment	**62**	**58**
SAKK trials	30	33
Trials with other cooperative groups/partners	32	25

The situation regarding the financial restructuring of SAKK and the resulting trial closures was discussed with Swissethics and representatives of the cantonal Ethics Committees at a joint meeting and the next course of action was determined.

Expansion of the responsibilities of the SAKK Safety Office

The scope of responsibility of the SAKK Safety Office at the SAKK CC was expanded in 2020. The Safety Office team is now responsible for handling safety signals sooner, from the time an SAE is received at the SAKK CC. The structure and processes were adapted accordingly. In addition, the foundation was laid for SAEs to be recorded electronically by the trial sites in secuTrial® in the future, with the aim of further digitalizing processes.

The work done by the SAKK Quality Assurance department was heavily impacted by COVID-19

Instead of performing audits in accordance with the annual plan, the emphasis of QA was on the many questions relating to trial activities in a pandemic situation. From February, rapid risk-based decisions had to be taken to determine which trials could remain open and under what conditions. International guidelines and national requirements documents were published on an ongoing basis, analyzed, and promptly implemented for SAKK trial activities. Numerous questions from the trial sites and trial teams concerning deviations from the planned procedure were rapidly processed to enable a compliant solution to be found for the specific situation. The situation eased temporarily in the summer of 2020. The good work done in the spring paid out during the second wave of the pandemic in the fall, enabling the treatment of cancer patients in clinical trials to proceed smoothly despite the more difficult conditions.

Dr. Stefanie Hayoz
Head of Statistics

Trial Results and Publications

Last year, 42 articles with SAKK participation appeared in various scientific journals. The full list can be found on page 64–69.

SAKK was well represented at the major oncology congresses as well as at more local events with 21 posters and 10 oral presentations, including a poster discussion at the Virtual Scientific Meeting of the American Society of Clinical Oncology (ASCO), two posters at the ASCO Genitourinary Cancers Symposium (ASCO GU 2020), and five posters and two oral presentations at the European Society for Medical Oncology (ESMO) Virtual Congress. A full list of all posters and presentations can be found on page 70–72.

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

The statistics team produced 26 clinical trial reports, including five final reports for the authorities.

Balance sheet

As of December 31 (in CHF)	**2020**		**2019**	
Assets				
Cash and cash equivalents	4'550'582		10'622'456	
Accounts receivable	3'339'791		4'693'599	
Other accounts receivable	63'486		66'247	
Prepaid expenses and deferred income	1'649'395		1'247'586	
Total current assets	**9'603'254**	36.3 %	**16'629'888**	61.8 %
Financial assets	16'833'328		10'301'022	
Total fixed assets	**16'833'328**	63.7 %	**10'301'022**	38.2 %
Total assets	**26'436'582**	100.0 %	**26'930'910**	100.0 %
Liabilities				
Accounts payable	3'450'751		3'491'014	
Other accounts payable	425'213		222'506	
Deferred income and accrued expenses	8'912'653		7'299'233	
Total short-term liabilities	**12'788'617**	48.4 %	**11'012'753**	40.9 %
Provisions for liability claims			–608'156	
Other Provisions	–		–	
Total long-term liabilities	**–**	–0.0 %	**608'156**	2.3 %
«Education Grant» fund	60'000		30'000	
«Special purpose» fund	217'932		217'932	
«Hubacher» fund	9'744'483		11'040'400	
Total special purpose fund capital	**10'022'415**	37.9 %	**11'288'332**	41.9 %
Organizational capital				
Free capital as at 1 January	4'021'669		4'232'020	
Group result	–396'118		–210'351	
Free capital as at 31 December	3'625'550		4'021'669	
Total organizational capital	**3 '625'550**	13.7 %	**4'021'669**	14.9 %
Total liabilities	**26'436'582**	100.0 %	**26'930'910**	100.0 %

Statement of operations

January 1 to December 31 (in CHF)	**2020**		**2019**	
Operating income				
Research contributions SERI[1]	6'094'734		5'836'218	
Research contributions CLS[2]	281'450		376'050	
Research contributions CRS[3]	1'781'250		2'340'350	
Research contributions SSKK[4]	100'000		100'000	
Research contributions, third parties	900'203		1'891'352	
Research contributions, Swiss health insurers	1'632'615		2'245'295	
Income from industry partnerships	3'620'933		8'426'982	
Income from foreign study groups	606'878		334'415	
Income from Cancer Bulletin	219'089		207'149	
Income from Patient Advisory Board	70'028		20'000	
Donations, bequests, legacies	1'948'483		349'574	
Miscellaneous income	1'218'793		974'359	
Losses on receivables	–21'999		–44'119	
Total operating income	**18'452'456**	100.0 %	**23'057'625**	100.0 %
Operating costs				
Miscellaneous study-related expenses	–2'059'058		–1'883'321	
Research contributions IBCSG, ETOP[5]	–295'942		–420'757	
Research contributions, centers	–5'669'183		–7'433'395	
Travel, hospitality expenses	–1'191'975		–1'061'277	
Other operating expenses	–124'718		–209'113	
Total operating expenses	**–9'340'877**	–50.6 %	**–11'007'863**	–47.7 %
Interim result 1	**9'111'579**	49.4 %	**12'049'762**	52.3 %
Coordination expenses				
Personnel expenses	–9'575'356		–9'636'039	
Other coordination expenses	–1'681'524		–1'929'614	
Total coordination expenses	**–11'256'880**	–61.0 %	**–11'565'654**	–50.2 %
Interim result 2	**–2'145'301**	–11.6 %	**484'108**	2.1 %
Financial result				
Financial income	221'160		32'969	
Financial expenses	–187'359		–77'428	
Total financial result	**33'801**	0.2 %	**–44'460**	–0.2 %
Interim result 3	**–2'111'500**	–11.4 %	**439'649**	1.9 %
Out-of-period result				
Out-of period income	1'880'379		–	
Out-of period expenses	–164'997		–650'000	
Total out-of-period result	1'715'382	9.3 %	–650'000	–2.8 %
Annual result	**–396'118**	–2.1 %	**–210'351**	–0.9 %

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 2020 annual financial statements

As of December 31	2020	2019
Information compliant with Art. 957–962 SCO		
Number of personnel		
Bandwidth of full-time equivalents (average for year)	>50 to 250	>50 to 250
Valuation of assets at market value		
Financial investments at market value on 31.12	16'833'328 CHF	10'301'022 CHF
Net accounts receivable	3'339'791 CHF	4'693'599 CHF
Deferred income and accrued expenses – material items		
Future payments SAKK 96/12	1'428'358 CHF	2'330'750 CHF
Ongoing study accruals and deferrals	4'664'726 CHF	1'283'000 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	69'073 CHF	81'825 CHF
Fixed rental contract (offices) up to 30.4.2026	1'445'045 CHF	1'715'991 CHF
Fixed rental contract (offices) up to 30.8.2027	577'734 CHF	664'394 CHF
Total	2'091'852 CHF	2'462'210 CHF
Notes on extraordinary, non-recurring or out-of-period items in the income statement		
Out-of-period expenses	–164'997 CHF	–650'000 CHF
Out-of-period income	1'880'379 CHF	0 CHF
Total	1'715'382 CHF	–650'000 CHF
Cost reductions as a result of the restructuring are included here.		
Net release of hidden reserves	273'853 CHF	0 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).

Events after the balance sheet date:
None

Measurement of research projects:
For the 2020 annual financial statements, research projects were for the first time measured in accordance with the principle of itemized measurement for long-term research projects, resulting in identifiable losses on individual studies through to 2027 (measurement at the lower of cost or market value). Losses occurring after that time are disregarded, as management expects to be able either to generate further funding for such projects by then or to terminate the projects early.

The project budgets prepared by the project managers responsible were used as the basis for measurement. These reflect the expected external project finance, or any fund withdrawals less the external and internal costs incurred up until then. In addition, the anticipated and undedicated federal financial contribution was allocated to the total capacity in proportion to the personnel hours budgeted for the projects affected by losses. It is assumed here that the federal funds in the next financing round will be of the same amount.

As of the reporting date, the sum total of all study losses calculated on the basis of itemized measurement means that 57.5 % of the committed federal financial contributions set out in the 2021–2024 multi-year plan were used. Asymmetrically incurred costs were taken sufficiently into account here.

Based on itemized measurement and the multi-year plan, a provision is not required to be recognized as of the reporting date in order to ensure that long-term research projects are measured at the lower of cost or market value.

As of the reporting date, the contributions from the SERI for 2021 to 2024 are approved.

RÖTHLISBERGER

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Report of the Statutory Auditor
to the General Assembly of

Swiss Group for Clinical Cancer Research, Berne

As statutory auditor, we have audited the accompanying financial statements of Swiss Group for Clinical Cancer Research, which comprise the balance sheet, the income statement, cash flow statement, the statement of changes in equity, the statement of changes in funds and notes for the year ended December 31, 2020.

Board's Responsibility

The Board is responsible for the preparation of these financial statements in accordance with the requirements of Swiss law and the bylaws. 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 of Directors 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 the accounting policies used and the reasonableness of accounting estimates made, as well as evaluating the overall

RÖTHLISBERGER

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 December 31, 2020 comply with Swiss law and the bylaws.

Other facts

The examination of the prior year financial statements was performed by another auditor who expressed an unmodified examination conclusion on those financial statements on April 3, 2020.

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 article 11 AOA) 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 of Directors.

We recommend that the financial statements submitted to you be approved.

We draw your attention to the fact, that contrary to art. 699 para. 2 CO the General Assembly has not been held within six months after the closing date of the financial year.

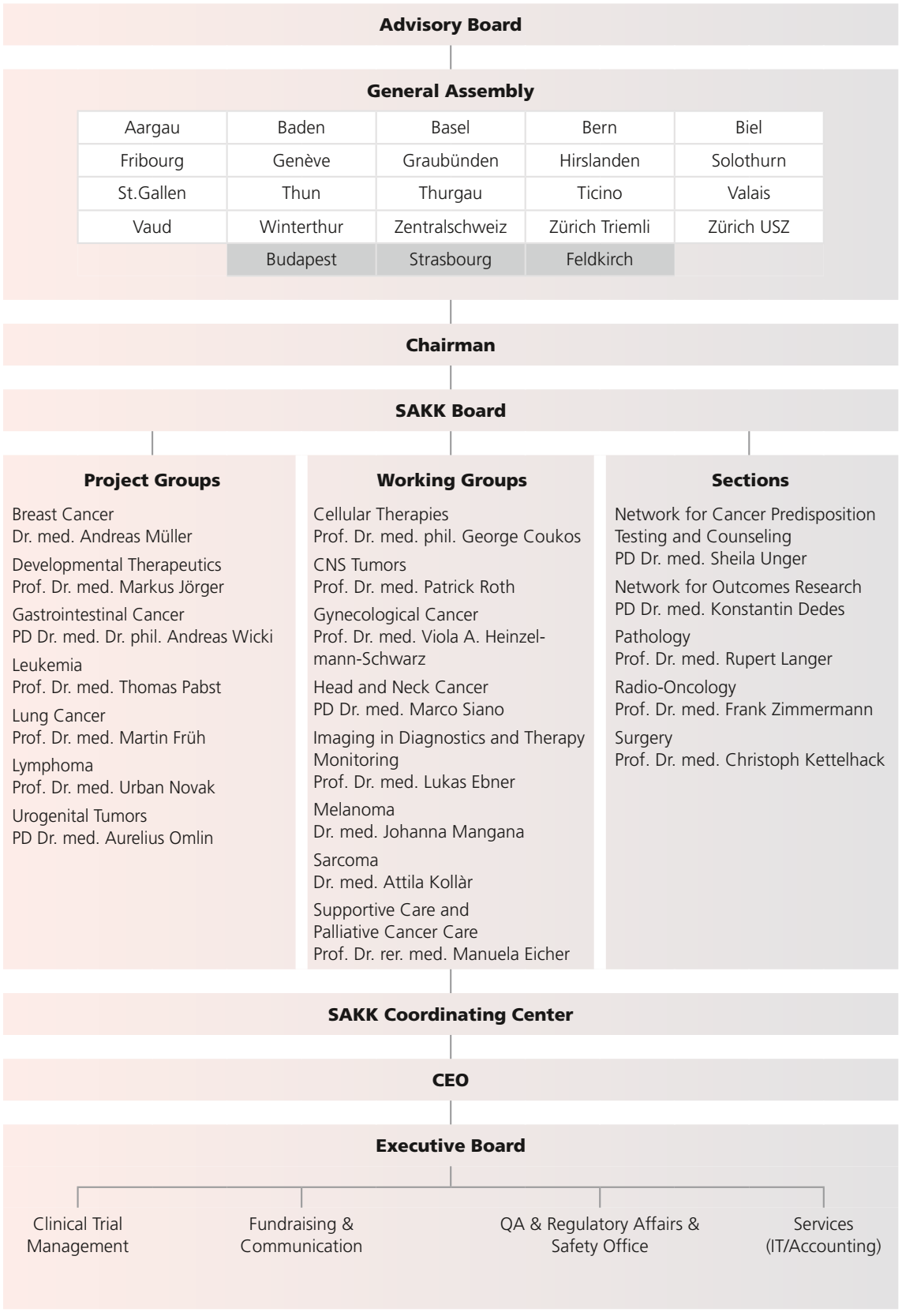
Berne, November 4, 2021 FC/ro
143400SAKK_RB_oR_2020_en

Dr. Röthlisberger AG

Fabrizio Conoscenti
Audit Expert
(Auditor in Charge)

Romano Jungo
Audit Expert

- Financial statements (balance sheet, the income statement, cash flow statement, the statement of changes in equity, the statement of changes in funds and notes)
  Balance sheet CHF 26'436'582 / Annual loss –CHF 396'118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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 (SCR)
– Swiss Cancer League (SCL)
– Administrative Commission for the Fund LOA IV/1
– Basel Cancer League (KLbB)
– 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 Medical
– Gateway for Cancer Research
– Hedy Glor-Meyer Stiftung
– ISREC Foundation
– Kämpf-Bötschi Stiftung
– Pink Ribbon
– Private donors, including Mr. Jahangir Doongaji
– Promedica
– Rising Tide Foundation for Clinical Cancer Research
– Schweizerische Stiftung für Klinische Krebsforschung (SSKK)
– Stiftung IQmed
– Stiftung zur Krebsbekämpfung
– Werner and Hedy Berger-Janser Foundation (Werner und Hedy Berger-Janser Stiftung zur Erforschung der Krebskrankheiten)

SAKK Industry Pool 2020

Sincere thanks to the following pharmaceutical companies for their support:

– AbbVie AG
– Amgen Switzerland AG
– Astellas Pharma AG
– AstraZeneca AG
– Bayer (Schweiz) AG
– Bristol-Myers Squibb SA / Celgene GmbH
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– Takeda 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 2020

Trials activated in 2020

Trial name	Trial title	Coordinating investigator	Activation
Breast Cancer			
SAKK 23/18	Vacuum assisted biopsy Immediately before Surgery as an Intra- or pre-Operative surrogate for patient response to Neoadjuvant chemotherapy for breast cancer (VISION I).	Christoph Tausch	30.06.2020
Developmental Therapeutics			
SAKK 66/17	Intratumoral injection of IP-001 following thermal ablation in patients with advanced solid tumors. A multicenter phase Ib/IIa trial with expansion cohorts in melanoma and soft tissue sarcoma patients.	Markus Jörger	02.07.2020
SCORED: SAKK 80/19	Alpine Tumor Immunology Registry.	Ulf Petrausch	06.02.2020
SCORED: SAKK 80/20	Outcome and prognostic factors of SARS CoV-2 infection in cancer patients: A cross-sectional study.	Markus Jörger	16.04.2020
Gastrointestinal Cancer			
DANTE	A randomized, open-label Phase II efficacy and safety study of atezolizumab in combination with FLOT versus FLOT alone in patients with gastric cancer and adenocarcinoma of the oesophago-gastric junction (MO30039) – The DANTE Trial.	Alexander Siebenhüner	10.01.2020
SAKK 44/19	Irreversible electroporation (IRE) followed by nivolumab in patients with metastatic pancreatic cancer: a multicenter single-arm phase II trial.	Mathias Worni	28.05.2020
Leukemia			
HOVON 156	HOVON 156 / AMLSG 28-18: A phase 3, multicenter, open-label, randomized, study of Gilteritinib versus Midostaurin in combination with induction and consolidation therapy followed by one-year maintenance in patients with newly diagnosed acute myeloid leukemia (AML) or myelodysplastic syndromes with excess blasts-2 (MDS-EB2) with FLT3 mutations eligible for intensive chemotherapy.	Thomas Pabst	15.10.2020
SAKK 33/18	I-CARE for MDS: Impact of Guidelines Adherence on Effectiveness and Safety of Health CARE Provided to MDS Patients.	Nicolas Bonadies	03.03.2020
Lung Cancer			
ACHILES	A randomized phase II study comparing atezolizumab after concurrent chemoradiotherapy with chemoradiotherapy alone in limited disease small-cell lung cancer.	Sacha Rothschild	29.01.2020
SAKK 16/18	Immune-modulatory radiotherapy to enhance the effects of neoadjuvant PD-L1 blockade and neodjuvant chemotherapy in patients with stage III(N2) non-small cell lung cancer (NSCLC). A multicenter single-arm phase II trial.	Laetitia Mauti	28.04.2020
Lymphoma			
IELSG-47	Phase II study of combination ibrutinib and rituximab in untreated marginal zone lymphomas.	Emanuele Zucca	13.02.2020

Trials open for accrual in 2020

Trial name	Trial title	Coordinating investigator	Activation
Breast Cancer			
IBCSG 55-17 TOUCH	Phase II open-label, multicenter, randomized trial of neo-adjuvant palbociclib in combination with hormonal therapy and HER2 blockade versus paclitaxel in combination 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
SAKK 21/18	Ribociclib-endocrine therapy combination versus chemotherapy 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 23/18	Vacuum assisted biopsy Immediately before Surgery as an Intra- or pre-Operative surrogate for patient response to Neoadjuvant chemotherapy for breast cancer (VISION I).	Christoph Tausch	30.06.2020
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
Developmental Therapeutics			
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 66/17	Intratumoral injection of IP-001 following thermal ablation in patients with advanced solid tumors. A multicenter phase Ib/IIa trial with expansion cohorts in melanoma and soft tissue sarcoma patients.	Markus Jörger	02.07.2020
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 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
SCORED: SAKK 80/19	Alpine Tumor Immunology Registry.	Ulf Petrausch	06.02.2020
SCORED: SAKK 80/20	Outcome and prognostic factors of SARS CoV-2 infection in cancer patients: A cross-sectional study.	Markus Jörger	16.04.2020

Trial name	Trial title	Coordinating investigator	Activation
Gastrointestinal Cancer			
DANTE	A randomized, open-label Phase II efficacy and safety study of atezolizumab in combination with FLOT versus FLOT alone in patients with gastric cancer and adenocarcinoma of the oesophago-gastric junction (MO30039) – The DANTE Trial.	Alexander Siebenhüner	10.01.2020
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 chemotherapy. 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 radiotherapy in locally advanced rectal cancer. A Phase Ib trial.	Sara Bastian	27.02.2017
SAKK 44/19	Irreversible electroporation (IRE) followed by nivolumab in patients with metastatic pancreatic cancer: a multicenter single-arm phase II trial.	Mathias Worni	28.05.2020
Gynecological Cancer			
ENGOT-en7_ AtTEnd	Phase III double-blind randomized placebo controlled trial of Atezolizumab in combination with Paclitaxel and Carboplatin in women with advanced/recurrent endometrial 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).	Viola A. Heinzelmann-Schwarz	03.06.2019
Head and Neck Cancer			
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-N1 oropharyngeal, supraglottic carcinoma and with T1, N0 hypopharyngeal carcinoma.	Frank Zimmermann	27.11.2017
Leukemia			
GRAALL 2014	Multicenter trial for the treatment of Acute Lymphoblastic Leukemia (ALL) in younger adults (18-59 years) – Comprising 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 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 myelodysplastic syndrome with excess blasts-2, with an IDH1 or IDH2 mutation, eligible for intensive chemotherapy	Markus G. Manz	05.12.2019

Trial name	Trial title	Coordinating investigator	Activation
HOVON 156	HOVON 156 / AMLSG 28-18: A phase 3, multicenter, open-label, randomized, study of Gilteritinib versus Midostaurin in combination with induction and consolidation therapy followed by one-year maintenance in patients with newly diagnosed acute myeloid leukemia (AML) or myelodysplastic syndromes with excess blasts-2 (MDS-EB2) with FLT3 mutations eligible for intensive chemotherapy.	Thomas Pabst	15.10.2020
SAKK 33/18	I-CARE for MDS: Impact of Guidelines Adherence on Effectiveness and Safety of Health CARE Provided to MDS Patients.	Nicolas Bonadies	03.03.2020
SAKK 34/17	Ibrutinib lead-in followed by venetoclax plus ibrutinib in patients with relapsed/refractory chronic lymphocytic leukemia. A multicenter, open-label, phase II trial.	Davide Rossi	21.02.2019
Lung Cancer			
ACHILES	A randomized phase II study comparing atezolizumab after concurrent chemoradiotherapy with chemoradiotherapy alone in limited disease small-cell lung cancer.	Sacha Rothschild	29.01.2020
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	28.02.2016
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 atezolizumab 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 16/18	Immune-modulatory radiotherapy to enhance the effects of neoadjuvant PD-L1 blockade and neodjuvant chemotherapy in patients with stage III(N2) non-small cell lung cancer (NSCLC). A multicenter single-arm phase II trial.	Laetitia Mauti	28.04.2020
SAKK 19/16	Binimetinib, pemetrexed and cisplatin, followed by maintenance 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
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

Trial name	Trial title	Coordinating investigator	Activation
Lymphoma			
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 BEA-COPP 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-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
IELSG-47	Phase II study of combination ibrutinib and rituximab in untreated marginal zone lymphomas.	Emanuele Zucca	13.02.2020
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
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
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
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 Tumors			
PEACE-4	A Phase III trial of acetylsalicylic acid and atorvastatin in patients with castrate-resistant prostate cancer.	Silke Gillessen	16.04.2019
SAKK 01/18	Reduced intensity radiochemotherapy for Stage IIA/B Seminoma.	Alexandros Papachristofilou	11.07.2019
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

Trial name	Trial title	Coordinating investigator	Activation
SAKK 08/16	Darolutamide (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

Trials closed for accrual in 2020

Trial name	Trial title	Coordinating investigator	Closure for accrual
Breast Cancer			
SAKK 95/17	A 24 weeks activity program in patients with early breast cancer receiving aromatase inhibitor therapy. A multi-center randomized phase III trial.	Nicolette Hoefnagels	30.10.2020
Developmental Therapeutics			
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	25.11.2020
SCORED: SAKK 80/20	Outcome and prognostic factors of SARS CoV-2 infection in cancer patients: A cross-sectional study.	Markus Jörger	12.11.2020
Gastrointestinal Cancer			
DANTE	A randomized, open-label Phase II efficacy and safety study of atezolizumab in combination with FLOT versus FLOT alone in patients with gastric cancer and adenocarcinoma of the oesophago-gastric junction (MO30039) – The DANTE Trial.	Alexander Siebenhüner	15.10.2020
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	25.11.2020
SAKK 41/13	Adjuvant aspirin treatment in PIK3CA mutated colon cancer patients. A randomized, double-blinded, placebo-controlled, phase III trial.	Ulrich Güller	25.11.2020
SAKK 41/14	Physical activity program in patients with metastatic colorectal cancer who receive palliative first-line chemotherapy. A multicenter open label randomized controlled trial.	Viviane Hess	25.11.2020
Gynecological Cancer			
ENGOT-en7_ AtTEnd	Phase III double-blind randomized placebo controlled trial of Atezolizumab in combination with Paclitaxel and Carboplatin in women with advanced/recurrent endometrial cancer.	Manuela Rabaglio-Poretti	25.11.2020
Leukemia			
SAKK 34/17	Ibrutinib lead-in followed by venetoclax plus ibrutinib in patients with relapsed/refractory chronic lymphocytic leukemia. A multicenter, open-label, phase II trial.	Davide Rossi	24.08.2020
Lung Cancer			
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	02.06.2020
ETOP ALERT	Single arm phase II trial evaluating the activity of Alectinib for the treatment of pretreated RET-rearranged advanced NSCLC.	Christian Britschgi	08.06.2020
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	30.11.2020
SAKK 19/16	Binimetinib, pemetrexed and cisplatin, followed by maintenance with binimetinib and pemetrexed, in patients with advanced non-small cell lung cancer with KRAS mutations. A multicenter phase IB trial.	Martin Früh	09.01.2020

Trial name	Trial title	Coordinating investigator	Closure for accrual
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	25.11.2020
Lymphoma			
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	22.06.2020
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	24.03.2020
TRIANGLE	Autologous Transplantation after a Rituximab/Ibrutinib/ Ara-c containing Induction in Generalized Mantle Cell Lymphoma – a randomized European MCL Network Trial.	Ulrich Mey	25.11.2020
Sarcoma			
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	24.06.2020
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	29.11.2020
Urogenital Tumors			
PEACE-4	A Phase III trial of acetylsalicylic acid and atorvastatin in patients with castrate-resistant prostate cancer.	Silke Gillessen	25.11.2020
SAKK 08/15	Multicenter, Randomized Phase II Trial of Salvage Radiotherapy +/- Metformin for Patients with Prostate Cancer after Prostatectomy.	Daniel M. Aebersold	25.11.2020
SAKK 08/16	Darolutamide (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	19.112020
SAKK 63/12	Prospective cohort study with collection of clinical data, serum and plasma of patients with prostate disease.	Daniel Engeler	25.11.2020

Patient Numbers Per Disease and Member

Breast Cancer	CNS Tumors	Developmental Therapeutics	Gastrointestinal Cancer	Gynecological Cancer	Head and Neck Cancer	Leukemia	Lung Cancer	Lymphoma	Melanoma	Sarcoma	Urogenital Tumors	Totals		
643	**9**	**50**	**145**	**37**	**24**	**110**	**181**	**249**	**32**	**28**	**388**	**1896**	Member	Sites
4	1	0	3	0	2	2	6	8	0	0	7	**33**	**Aargau**	**Kantonsspital Aarau**
16	0	1	8	5	0	2	4	7	2	0	8	**53**	**Baden**	**Kantonsspital Baden**
54	0	2	13	9	1	12	13	23	5	3	57	**192**	**Basel**	**Basel Bethesda Spital; Brustzentrum Basel – Praxis Thorn; Caba Zentrum für Onkologie, Psychologie und Bewegung; Claraspital; Gesundheitszentrum Fricktal; Kantonsspital Baselland Bruderholz; Kantonsspital Baselland Liestal; Onkopraxis Dr. med. A. Dieterle; Universitätsspital Basel**
9	0	1	6	2	2	21	15	49	0	7	23	**135**	**Bern**	**Inselspital; Lindenhofgruppe – Engeriedspital; Lindenhofgruppe – Sonnenhofspital**
1	1	0	1	2	0	0	0	0	0	0	0	**5**	**Biel**	**Spitalzentrum Biel**
42	0	1	8	0	1	10	6	13	2	0	8	**91**	**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**
34	2	12	6	0	2	7	9	8	2	1	24	**107**	**Genève**	**Clinique des Grangettes; Hôpitaux Universitaires de Genève; Praxis Dr. med E. Tullen; Praxis Dr. med. A. Hügli**
25	0	7	10	0	0	5	35	12	4	5	65	**168**	**Graubünden**	**Kantonsspital Graubünden; Tumorzentrum ZeTuP Chur**
95	0	1	8	0	1	1	16	13	3	1	17	**156**	**Hirslanden**	**Brustzentrum (Seefeld); Brustzentrum Bern Biel; Brustzentrum Ostschweiz; Hirslanden Klinik Hirslanden; Hirslanden Klinik Im Park; Hirslandenklinik Aarau; Hirslandenklinik Andreasklinik Cham Zug; Hirslandenklinik St. Anna; Onkologie Bellevue; Onkozentrum Hirslanden Zürich; Onkozentrum Zürich; Spital Zollikerberg; Tumorzentrum Aarau – Hirslanden Medical Center**
9	0	0	4	0	0	0	2	6	0	0	1	**22**	**Solothurn**	**Bürgerspital Solothurn – Solothurner Spitäler; Kantonsspital Olten – Solothurner Spitäler**
47	1	14	3	0	0	10	18	31	0	2	35	**161**	**St.Gallen**	**Kantonsspital St.Gallen; Rundum Onkologie am Bahnhofpark; Tumor- und Brustzentrum ZeTuP; ZeTuP Rapperswil-Jona**
8	0	0	2	0	0	0	2	1	0	0	2	**15**	**Thun**	**Radio-Onkologie Berner Oberland AG; Spital STS AG Thun**
21	0	0	2	4	1	4	0	4	1	0	3	**40**	**Thurgau**	**Network – Spital Thurgau; Spital Thurgau - Kantonsspital Frauenfeld; Spital Thurgau – Kantonsspital Münsterlingen**
27	1	6	15	4	2	5	22	24	3	2	34	**145**	**Ticino**	**Clinica Luganese; EOC – Istituto Oncologico della Svizzera Italiana; Fondazione Oncologia Lago Maggiore; Oncologia Varini&Calderoni**
17	0	0	7	1	0	0	0	0	0	0	9	**34**	**Valais**	**Hôpital du Valais, Hôpital de Sion; Hôpital du Valais, Spital Brig; Network – Hôpitaux du Valais**
42	3	3	15	5	10	3	14	11	9	2	7	**124**	**Vaud**	**CCAC – Centre de Chimiothérapie Anti-Cancéreuse; CHUV – Centre hospitalier universitaire vaudois; Clinique de Genolier**
30	0	0	10	1	0	1	8	4	0	1	10	**65**	**Winterthur**	**Kantonsspital Winterthur**
7	0	0	2	1	0	7	2	7	0	1	6	**33**	**Zentralschweiz**	**Luzerner Kantonsspital Luzern**
10	0	0	3	0	0	2	1	3	0	0	17	**36**	**Zürich Triemli**	**Spital Limmattal; Stadtspital Triemli**
20	0	2	7	3	2	18	8	5	1	3	15	**84**	**Zürich USZ**	**Spital Männedorf; Universitätsspital Zürich**
125	0	0	12	0	0	0	0	20	0	0	40	**197**	**Total Foreign Countries**	

Publications by SAKK and Cooperative Groups 2020

Trial name	Trial title	Authors	Journal	IF*
	Local regression smoothers with set-valued outcome data.	Li Q, Molchanov I, Molinari F, Peng S	INT J APPROX REASON	2.678
	The modified PFS ratio is not ready for prime time.	Kopp C, Li Q, Hayoz S	ESMO OPEN	5.329
Breast Cancer				
IBCSG 18-98	Cumulative incidence of cardiovascular events under tamoxifen and letrozole alone and in sequence: a report from the BIG 1-98 trial.	Rabaglio M, Sun Z, Maibach R, Giobbie-Hurder A, Ejlertsen B, Harvey VJ, Neven P, Láng I, Bonnefoi H, Wardley A, Ruepp B, Castiglione M, Coates AS, Gelber RD, Goldhirsch A, Colleoni M, Thürlimann B, Regan MM	BREAST CANCER RES TR	3.94
IBCSG 18-98	Identifying oncogenic drivers associated with increased risk of late distant recurrence in postmenopausal, estrogen receptor-positive, HER2-negative early breast cancer: results from the BIG 1-98 study.	Luen SJ, Asher R, Lee CK, Savas P, Kammler R, Dell'Orto P, Biasi OM, Demanse D, Hackl W, Thuerlimann B, Viale G, Di Leo A, Colleoni M, Regan MM, Loi S	ANN ONCOL	18.274
SAKK 21/08	Cardiovascular safety of BRAF and/or MEK inhibitors in cancer patients: A mixed approach combining a meta-analysis of placebo randomized-controlled trials and a WHO pharmacovigilance disproportionality analysis.	Dolladille C, Font J, Bejan-Angoulvant T, Zaman K, Sassier M, Ezine E, Stefan A, Plane AF, Legallois D, Milliez P, Parienti JJ, Alexandre J	ARCH CARDIO-VASCULAR DIS	2.271
SAKK 22/99	Plasma HER2ECD a promising test for patient prognosis and prediction of response in HER2 positive breast cancer: results of a randomized study – SAKK 22/99.	Eppenberger-Castori S, Klingbiel D, Ruhstaller T, Dietrich D, Rufle DA, Rothgiesser K, Pagani O, Thürlimann B	BMC CANCER	2.933
Gastrointestinal Cancer				
SAKK 75/08	High thromboembolic event rate in patients with locally advanced oesophageal cancer during neoadjuvant therapy. An exploratory analysis of the prospective, randomised intergroup phase III trial SAKK 75/08.	Fehr M, Hawle H, Hayoz S, Thuss-Patience P, Schacher S, Riera Knorrenschild J, Dürr D, Knoefel WT, Rumpold H, Bitzer M, Zweifel M, Samaras P, Mey U, Küng M, Winterhalder R, Eisterer W, Hess V, Gérard MA, Templeton A, Stahl M, Ruhstaller T	BMC CANCER	3.362
SAKK 75/08	Surgical outcomes after neoadjuvant chemoradiation followed by curative surgery in patients with esophageal cancer: An intergroup phase lll trial of the Swiss Group for Clinical Cancer Research (SAKK 75/08).	von Holzen U, Schmidt S, Hayoz S, Steffen T, Grieder F, Bartsch D, Schnider A, Knoefel WT, Piessen G, Kettelhack C, Marti WR, Schäfer M, Függer R, Königsrainer A, Gloor B, Furrer M, Gérard MA, Hawle H, Walz MK, Alesina P, Ruhstaller T	ANN SURG	10.13
Gynecological Cancer				
AGO-OVAR	Atezolizumab in combination with bevacizumab and chemotherapy versus bevacizumab and chemotherapy in recurrent ovarian cancer – a randomized phase III trial (AGO-OVAR 2.29/ENGOT-ov34)	Harter P, Pautier P, Van Nieuwenhuysen E, Reuss A, Redondo A, Lindemann K, Kurzeder C, Petru E, Heitz F, Sehouli J, Degregorio N, Wimberger P, Burges A, Cron N, Ledermann J, Lorusso D, Paoletti X, Marme F	INT J GYNECOL CANCER	2.095

Trial name	Trial title	Authors	Journal	IF*
Leukemia				
CLL 10	Long Term Follow-up Data and Health-Related Quality of Life in Frontline Therapy of Fit Patients Treated With FCR Versus BR (CLL10 Trial of the GCLLSG).	Kutsch N, Bahlo J, Robrecht S, Franklin J, Zhang C, Maurer C, De Silva N, Lange E, Weide R, Kiehl MG, Sökler M, Schlag R, Vehling-Kaiser U, Köchling G, Plöger C, Gregor M, Plesner T, Herling M, Fischer K, Döhner H, Kneba M, Wendtner CM, Klapper W, Kreuzer KA, Böttcher S, Stilgenbauer S, Fink AM, Hallek M, Eichhorst B	HEMAS-PHERE	.
CLL 7	Early treatment with FCR versus watch and wait in patients with stage Binet A high-risk chronic lymphocytic leukemia (CLL): a randomized phase 3 trial.	Herling CD, Cymbalista F, Gross-Ophoff-Müller C, Bahlo J, Robrecht S, Langerbeins P, Fink AM, Al-Sawaf O, Busch R, Porcher R, Cazin B, Dreyfus B, Ibach S, Leprêtre S, Fischer K, Kaiser F, Eichhorst B, Wentner CM, Hoechstetter MA, Döhner H, Leblond V, Kneba M, Letestu R, Böttcher S, Stilgenbauer S, Hallek M, Levy V	LEUKEMIA	8.665
CML-IV	High-risk additional chromosomal abnormalities at low blast counts herald death by CML.	Hehlmann R, Voskanyan A, Lauseker M, Pfirrmann M, Kalmanti L, Rinaldetti S, Kohlbrenner K, Haferlach C, Schlegelberger B, Fabarius A, Seifarth W, Spiess B, Wuchter P, Krause S, Kolb HJ, Neubauer A, Hossfeld DK, Nerl C, Gratwohl A, Baerlocher GM, Burchert A, Brümmendorf TH, Hasford J, Hochhaus A, Saussele S, Baccarani M	LEUKEMIA	10.431
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 2005	Thromboembolism Prophylaxis in Adult Patients with Acute Lympho-blastic Leukemia Treated in the GRAALL-2005 Study.	Orvain C, Balsat M, Tavernier E, Marolleau JP, Pabst T, Chevallier P, de Gunzburg N, Cacheux V, Rigal-Huguet F, Chantepie SP, Caillot D, Chalandon Y, Frayfer J, Bonmati C, Lheritier V, Ifrah NH, Dombret H, Boissel N, Hunault-Berger MM	BLOOD	10.452
HD13, HD14, HD15	Health-Related Quality of Life in Patients With Hodgkin Lymphoma: A Longitudinal Analysis of the German Hodgkin Study Group.	Kreissl S, Müller H, Goergen H, Meissner J, Topp M, Sökler M, Markova J, Bernhard J, Greil R, von Tresckow B, Behringer K, Rüffer JU, Flechtner HH, Möstl M, Fuchs M, Engert A, Diehl V, Borchmann P	J CLIN ONCOL	32.956

Trial name	Trial title	Authors	Journal	IF*
HOVON 103 – LEN	Lenalidomide added to standard intensive treatment for elderly patients with AML and high risk MDS.	Ossenkoppele GJ, Breems DA, Stuessi G, van Norden Y, Bargetzi M, Biemond BJ, A von dem Borne P, Chalandon Y, Cloos J, Deeren D, Fehr M, Gjertsen B, Graux C, Huls G, Janssen JJJW, Jaspers A, Jongen-Lavrencic M, de Jongh E, Klein SK, van der Klift M, van Marwijk Kooy M, Maertens J, Micheaux L, van der Poel MWM, van Rhenen A, Tick L, Valk P, Vekemans MC, van der Velden WJFM, de Weerdt O, Pabst T, Manz M, Löwenberg B	LEUKEMIA	10.431
HOVON 135	Ibrutinib added to 10-day decitabine for older patients with AML and higher-risk MDS.	Huls G, Chitu DA, Pabst T, Klein SK, Stussi G, Griskevicius L, Valk PJM, Cloos J, van de Loosdrecht AA, Breems D, van Lammeren-Venema D, van Zeventer I, Boersma R, Jongen-Lavrencic M, Fehr M, Hoogendoorn M, Manz MG, Söhne M, van Marwijk Kooy R, Deeren D, van der Poel MWM, Legdeur MC, Tick L, Chalandon Y, Ammatuna E, Blum S, Löwenberg B, Ossenkoppele GJ	BLOOD ADV	4.91
SAKK 32/93, 32/95, 32/98	Prospective long-term follow-up after first-line subcutaneous cladribine in hairy cell leukemia – A SAKK trial.	Benz R, Arn K, Andres M, Pabst T, Baumann M, Novak U, Hitz F, Hess U, Zenhaeusern R, Chalandon Y, Mey U, Blum S, Rauch D, O'Meara Stern A, Cantoni N, Bargetzi M, Bianchi-Papina E, Rossi D, Passweg J, Lohri A, Berardi S, Li Q, Feller A, Stussi G	BLOOD ADV	4.91
SAKK 33/18	Guideline-based indicators for adult patients with myelodysplastic syndromes.	Stojkov K, Silzle T, Stussi G, Schwappach D, Bernhard J, Bowen D, Cermák J, Dinmohamed AG, Eeltink C, Eggmann S, Fenaux P, Germing U, Haschke M, Hellstrom-Lindberg E, Heger M, van de Loosdrecht AA, Passweg J, Pfeilstöcker M, Platzbecker U, Malcovati L, de Almeida AM, Mittelman M, Morgenthaler C, Steensma DP, Santini V, Stauder R, Symeonidis A, Schär S, Maddox C, de Witte T, Bohlius J, Bonadies N	BLOOD ADV	4.91
Lung Cancer				
	Outcomes with immune checkpoint inhibitors for relapsed small-cell lung cancer in a Swiss cohort.	Schmid S, Mauti LA, Friedlaender A, Blum V, Rothschild SI, Bouchaab H, Frösch P, Britschgi C, König D, Wannesson L, Janthur WD, Schär S, Demmer I, Addeo A, Jochum W, Früh M	CANCER IMMUNOL IMMUN	4.9
ETOP PROMISE-meso	A multicentre randomised phase III trial comparing pembrolizumab versus single-agent chemotherapy for advanced pre-treated malignant pleural mesothelioma: the European Thoracic Oncology Platform (ETOP 9–15) PROMISE-meso trial.	Popat S, Curioni-Fontecedro A, Dafni U, Shah R, O'Brien M, Pope A, Fisher P, Spicer J, Roy A, Gilligan D, Gautschi O, Nadal E, Janthur WD, López Castro R, García Campelo R, Rusakiewicz S, Letovanec I, Polydoropoulou V, Roschitzki-Voser H, Ruepp B, Gasca-Ruchti A, Peters S, Stahel RA	ANN ONCOL	18.274

Trial name	Trial title	Authors	Journal	IF*
ETOP SPLENDOUR	A Randomized Open-Label Phase III Trial Evaluating the Addition of Denosumab to Standard First-Line Treatment in Advanced NSCLC: The European Thoracic Oncology Platform (ETOP) and European Organisation for Research and Treatment of Cancer (EORTC) SPLENDOUR Trial.	Peters S, Danson S, Hasan B, Dafni U, Reinmuth N, Majem M, Tournoy KG, Mark MT, Pless M, Cobo M, Rodriguez-Abreu D, Falchero L, Moran T, Ortega Granados AL, Monnet I, Mohorcic K, Sureda BM, Betticher D, Demedts I, Macias JA, Cuffe S, Luciani A, Sanchez JG, Curioni-Fontecedro A, Gautschi O, Price G, Coate L, von Moos R, Zielinski C, Provencio M, Menis J, Ruepp B, Pochesci A, Roschitzki-Voser H, Besse B, Rabaglio M, O'Brien MER, Stahel RA	J THORAC ONCOL	13.357
	A cost-effectiveness analysis of consolidation immunotherapy with durvalumab in stage III NSCLC responding to definitive radiochemotherapy in Switzerland.	Panje CM, Lupatsch JE, Barbier M, Pardo E, Lorez M, Dedes KJ, Aebersold DM, Plasswilm L, Gautschi O, Schwenkglenks M	ANN ONCOL	7.04
SAKK 15/12	Impact of early prophylactic cranial irradiation with hippocampal avoidance on neurotoxicity and quality of life in patients with limited disease small-cell lung cancer. A multicenter phase II trial (SAKK 15/12).	Vees H, Caparrotti F, Eboulet EI, Xyrafas A, Fuhrer A, Meier U, Mark M, Elicin O, Aebersold DM, Zwahlen DR, Finazzi T, Allal AS, Putora PM, Martucci F, Rudolf CB, Ribi K	INT J RADIAT ONCOL BIOL PHYS	6.203
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 16/00	Comparison of robust to standardized CT radiomics models to predict overall survival for non-small cell lung cancer patients.	Vuong D, Bogowicz M, Denzler S, Oliveira C, Foerster R, Amstutz F, Gabryś HS, Unkelbach J, Hillinger S, Thierstein S, Xyrafas A, Peters S, Pless M, Guckenberger M, Tanadini-Lang S	MED PHYS	3.177
SAKK 16/00	Radiomics feature activation maps as a new tool for signature interpretability "for the special issue" Breakthrough in Imaging-Guided Precision Medicine in Oncology.	Vuong D, Tanadini-Lang S, Wu Z, Marks R, Unkelbach J, Hillinger S, Eboulet EI, Thierstein S, Peters S, Pless M, Guckenberger M, Bogowicz M	FRONT ONCOL	4.848
SAKK 19/09	Chemotherapy negatively impacts the tumor immune microenvironment in NSCLC: An analysis of pre and post treatment biopsies in the multi-center SAKK19/09 study.	Amrein MA, Bührer ED, Amrein ML, Li Q, Rothschild S, Riether C, Jaggi R, Savic-Prince S, Bubendorf L, Gautschi O, Ochsenbein AF	CANCER IMMUNOL IMMUN	4.711
SAKK 19/17	SAKK 19/17 – Is First-Line Durvalumab in Patients with PD-L1 Positive, Advanced Non-Small Cell Lung Cancer with a Performance Status of 2 Safe?	Mark M, Froesch P, Eboulet EI, Addeo A, Pless M, Rothschild SI, Janthur WD, Burmeister H, Friedlaender A, Schneider M, Metaxas Y, Joerger M, Wannesson L, Schwitter M, Baudoux N, Weindler S, Biaggi-Rudolf C, Früh M	CANCER IMMUNOL IMMUN	5.442

Trial name	Trial title	Authors	Journal	IF*
Lymphoma				
	A randomized evaluation of vinorelbine versus gemcitabinechemotherapy mobilization of stem cells in myeloma patients.	Jeker B, Farag S, Taleghani BM, Novak U, Mueller BU, Li Q, Betticher D, Luethi JM, Farese S, Ruefer A, Bacher U, Pabst T	BONE MARROW TRANSPL	3.57
EMN-02 Hovon 95	Autologous haematopoietic stem-cell transplantation versus bortezomib-melphalan-prednisone, with or without bortezomib-lenalidomide-dexamethasone consolidation therapy, and lenalidomide maintenance for newly diagnosed multiple myeloma (EMN02/HO95): a multicentre, randomised, open-label, phase 3 study.	Cavo M, Gay F, Beksac M, Pantani L, Petrucci MT, Dimopoulos MA, Dozza L, van der Holt B, Zweegman S, Oliva S, van der Velden VHJ, Zamagni E, Palumbo GA, Patriarca F, Montefusco V, Galli M, Maisnar V, Gamberi B, Hansson M, Belotti A, Pour L, Ypma P, Grasso M, Croockewit A, Ballanti S, Offidani M, Vincelli ID, Zambello R, Liberati AM, Andersen NF, Broijl A, Troia R, Pascarella A, Benevolo G, Levin MD, Bos G, Ludwig H, Aquino S, Morelli AM, Wu KL, Boersma R, Hajek R, Durian M, von dem Borne PA, Caravita di Toritto T, Driessen C, Specchia G, Waage A, Gimsing P, Mellqvist UH, van Marwijk Kooy M, Minnema M, Mandigers C, Cafro AM, Palmas A, Carvalho S, Spencer A, Boccadoro M, Sonneveld P	LANCET HAEMATOL	10.698
HD 10, HD 13	Relapse after Early-Stage Favorable Hodgkin Lymphoma: Disease Characteristics and Outcomes with Conventional or High-Dose Chemotherapy.	Bröckelmann PJ, Müller H, Guhl T, Behringer K, Fuchs M, Moccia AA, Rank A, Soekler M, Vieler T, Pabst T, Baues C, von Tresckow B, Borchmann P, Engert A	J CLIN ONCOL	18.428
T-Cell Project	Survival outcomes of patients with extranodal natural-killer T-cell lymphoma: a prospective cohort study from the international T-cell Project.	Fox CP, Civallero M, Ko YH, Manni M, Skrypets T, Pileri S, Kim SJ, Cabrera ME, Shustov AR, Chiattone CS, Horwitz SM, Dlouhy I, Spina M, Hitz F, Montoto S, Nagler A, Martinez V, De Souza CA, Fernandez-Alvarez R, Ballova V, Gabús R, Inghirami G, Federico M, Kim WS	LANCET HAEMATOL	10.698
SAKK 35/03	Prolonged rituximab maintenance in follicular lymphoma patients: Long-term results of the SAKK 35/03 randomized trial.	Moccia AA, Taverna C, Schär S, Vanazzi A, Rondeau S, Hitz F, Mingrone W, Pabst T, Cevreska L, Del Giglio A, Raats J, Rauch D, Vorobiof DA, Lohri A, Ruegsegger C, Biaggi Rudolf C, Rusterholz C, Hayoz S, Ghielmini M, Zucca E	BLOOD ADV	4.91
SAKK 35/10	Immunomodulatory drugs may overcome the negative prognostic role of active Th17 axis in follicular lymphoma: evidence from the SAKK35/10 trial.	Menter T, Hayoz S, Zucca E, Kimby E, Dirnhofer S, Tzankov A	BRIT J HAEMATOL	5.401
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

Trial name	Trial title	Authors	Journal	IF*
SAKK 35/98, 35/03, 35/10	Prognostic 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).	Moccia AA , Schär S, Hayoz S, Pirosa MC, Taverna C, Novak U, Kimby E, Ghielmini M, Zucca E	BRIT J HAEMATOL	5.67
SAKK 38/07	Prognostic models integrating quantitative parameters from baseline and interim positron emission computed tomography in patients with diffuse large B-cell lymphoma: post-hoc analysis from the SAKK38/07 clinical trial.	Zucca E, Cascione L, Ruberto T, Facchinelli D, Schär S, Hayoz S, Dirnhofer S, Giovanella L, Bargetzi M, Mamot C, Ceriani L	HEMATOL ONCOL	3.084
SAKK 38/07	SAKK38/07 study: integration of baseline metabolic heterogeneity and metabolic tumor volume in DLBCL prognostic model.	Ceriani L, Gritti G, Cascione L, Pirosa MC, Polino A, Ruberto T, Stathis A, Bruno A, Moccia AA, Giovanella L, Hayoz S, Schär S, Dirnhofer S, Rambaldi A, Martinelli G, Mamot C, Zucca E	BLOOD ADV	4.584
Urogenital Tumors				
	Activity of Platinum-Based Chemotherapy in Patients With Advanced Prostate Cancer With and Without DNA Repair Gene Aberrations.	Schmid S, Omlin A, Higano C, Sweeney C, Martinez Chanza N, Mehra N, Kuppen MCP, Beltran H, Conteduca V, Vargas Pivato de Almeida D, Cotait Maluf F, Oh WK, Tsao CK, Sartor O, Ledet E, Di Lorenzo G, Yip SM, Chi KN, Bianchini D, De Giorgi U, Hansen AR, Beer TM, Lavaud P, Morales-Barrera R, Tucci M, Castro E, Karalis K, Bergman AM, Le ML, Zürrer-Härdi U, Pezaro C, Suzuki H, Zivi A, Klingbiel D, Schär S, Gillessen S	JAMA NETW OPEN	5.032
	Reply by Authors.	Fankhauser CD, Grogg JB, Hayoz S, Wettstein MS, Dieckmann KP, Sulser T, Bode PK, Clarke NW, Beyer J, Hermanns T	J UROLOGY	5.647
SAKK 06/14	Results of the phase I open label clinical trial SAKK 06/14 assessing safety of intravesical instillation of VPM1002BC, a recombinant mycobacterium Bacillus Calmette Guérin (BCG), in patients with non-muscle invasive bladder cancer and previous failure of conventional BCG therapy.	Rentsch CA, Bosshard P, Mayor G, Rieken M, Püschel H, Wirth G, Cathomas R, Parzmair GP, Grode L, Eisele B, Sharma H, Gupta M, Gairola S, Shaligram U, Goldenberger D, Spertini F, Audran R, Enoiu M, Berardi S, Hayoz S, Wicki A	ONCOIMMUNOLOGY	5.333

Presentation of SAKK Trials (Without Cooperative Groups)

American Society of Clinical Oncology (ASCO) Annual Meeting

Poster discussion

Rothschild S. et al. 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.

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

Poster

Cathomas R. et al. Perioperative chemo-immunotherapy with durvalumab (Durva) in combination with cisplatin/gemcitabine (Cis/Gem) for operable muscle-invasive urothelial carcinoma (MIUC): preplanned interim analysis of a single arm phase II trial (SAKK 06/17).

Poster

Papachristofilou A. et al. Treatment compliance and early toxicity in SAKK 01/10: single dose carboplatin and involved-node radiotherapy for treatment of stage IIA/B seminoma.

American Society for Radiation Oncology (ASTRO) Annual Meeting

Poster

Beck M. Contouring Quality and Adherence to EORTC-based Protocol Guidelines in the Randomized Phase III SAKK 09/10 Trial for Postoperative Prostate Cancer Radiotherapy: Implications for Treatment Quality and Future Clinical Trials.

104th Annual Meeting of the German Society for Pathology (Jahrestagung der Deutschen Gesellschaft für Pathologie DGP)

Oral presentation

Menter T. et al. Analysis of the microenvironment of follicular lymphoma by gene expression analysis of the trial SAKK 35/10: importance of the Th17 axis.

72nd Congress of the German Society for Urology (Kongress der Deutschen Gesellschaft für Urologie DGU)

Oral presentation

Rentsch C. et al. Results of a phase II single arm clinical trial assessing efficacy, safety and tolerability of the recombinant Bacillus Calmette Guérin (BCG) VPM1002BC in patients with BCG failure – SAKK 06/14.

European Association of Urology (EAU) Congress

Poster

Rentsch C. et al. Results of a phase II single arm clinical trial assessing efficacy, safety and tolerability of the recombinant Bacillus Calmette Guérin (BCG) VPM1002BC in patients with BCG failure – SAKK 06/14.

European Hematology Association (EHA) Congress

Oral presentation

Zucca E. et al. Quantitative Parameters from Interim PET/CT after two R-CHOP14 Cycles identify poor-risk DLBCL Patients: Results from the Prospective SAKK 38/07 Clinical Study.

Poster

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

Poster

Stojkov K. et al. GUIDELINE-BASED INDICATORS FOR ADULT PATIENTS WITH MYELODYSPLASTIC SYNDROMES.

European Society for Medical Oncology (ESMO) Congress

Oral presentation
Jörger M. et al. Outcome and prognostic factors of SARS CoV-2 infection in cancer patients: A cross-sectional study (SAKK 80/20 CaSA).

Oral presentation
Rothschild S. et al. SAKK 16/14: Anti-PD-L1 antibody durvalumab in addition to neoadjuvant chemotherapy in patients with stage IIIA(N2) non-small cell lung cancer (NSCLC) – A multicenter single-arm phase II trial.

Poster
Früh M. et al. Binimetinib, pemetrexed (Pem) and cisplatin (Cis), followed by maintenance of Binimetinib and Pem in patients with advanced non-small cell lung cancer (NSCLC) and KRAS mutations. The phase 1B SAKK 19/16 trial.

Poster
Hasler-Strub U. et al. Optimal Dose of Eribulin as 1st Line Treatment in Elderly Patients = 70 Years with Advanced Breast Cancer: A Multicenter Phase II Trial (SAKK 25/14).

Poster
Hess D. et al. TLD-1, a novel liposomal doxorubicin, in patients (pts) with advanced solid tumors: dose escalation part of a multicenter open-label phase I trial (SAKK 65/16).

Poster
Ribi K. et al. Quality of life and pain in patients with metastatic bone disease from solid tumors treated with bone-targeted agents – a real-world cross-sectional study from Switzerland (SAKK 95/16).

Poster
Stenner F. et al. Optimizing Ipilimumab in RCC – Results from the SAKK 07/17 Nivolumab (N) + Ipilimumab (I) in mRCC.

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

Poster
Weber W. et al. Tailored axillary surgery with or without axillary lymph node dissection followed by radiotherapy in patients with clinically node-positive breast cancer (SAKK 23/16 / IBCSG 57–18 / ABCSG-53 / GBG 101 – TAXIS): a multicenter randomized phase III trial.

The European Society for Radiotherapy and Oncology (ESTRO)

Oral presentation
Vees H. et al. Neurotoxicity of early prophylactic cranial radiation and hippocampal avoidance in LD SCLC (SAKK 15/12).

Poster discussion
Vuong D. et al. New voxel-based approach to study the relation of tumor location and survival in NSCLC (SAKK 16/00).

International Bladder Cancer Network (IBCN) Annual Meeting

Oral presentation
Rentsch C. et al. Results of a phase I/II single arm clinical trial assessing efficacy, safety and tolerability of the recombinant Bacillus Calmette Guérin (rBCG) VPM1002BC in patients with high-grade non muscle-invasive bladder cancer recurrence after BCG induction with or without BCG maintenance therapy – SAKK 06/14.

San Antonio Breast Cancer Symposium (SABCS)

Poster discussion

Weber W. et al. Tailored axillary surgery to omit axillary lymph node dissection independently from the use of neoadjuvant chemotherapy in patients with clinically node-positive breast cancer: Pre-specified subproject within TAXIS (SAKK 23/16 / IBCSG 57–18 / ABCSG-53 / GBG 101).

Poster

Schwitter M. et al. Ribociclib-endocrine therapy (ET) combination versus chemotherapy as 1st line treatment in patients (pts) with visceral metastatic breast cancer (BC). A multicenter, randomized phase III trial: SAKK 21/18.

Poster

Weber W. et al. Tailored axillary surgery with or without axillary lymph node dissection followed by radiotherapy in patients with clinically node-positive breast cancer (SAKK 23/16 / IBCSG 57–18 / ABCSG-53 / GBG 101 – TAXIS): a multicenter randomized phase III trial.

Scientific Association of Swiss Radiation Oncology (SASRO) Annual Meeting

Oral presentation

Vuong D. et al. Radiomics activation maps as a new tool for signature interpretability.

Swiss Oncology and Hematology Congress (SOHC)

Oral presentation

Papachristofilou A. et al. Treatment compliance and early toxicity in SAKK 01/10: single dose carboplatin and involved-node radiotherapy for treatment of stage IIA/B seminoma.

Oral presentation

Rothschild S. et al. SAKK 16/14: Anti-PD-L1 antibody durvalumab in addition to neoadjuvant chemotherapy in patients with stage IIIA(N2) non-small cell lung cancer (NSCLC) – A multicenter single-arm phase II trial.

Poster

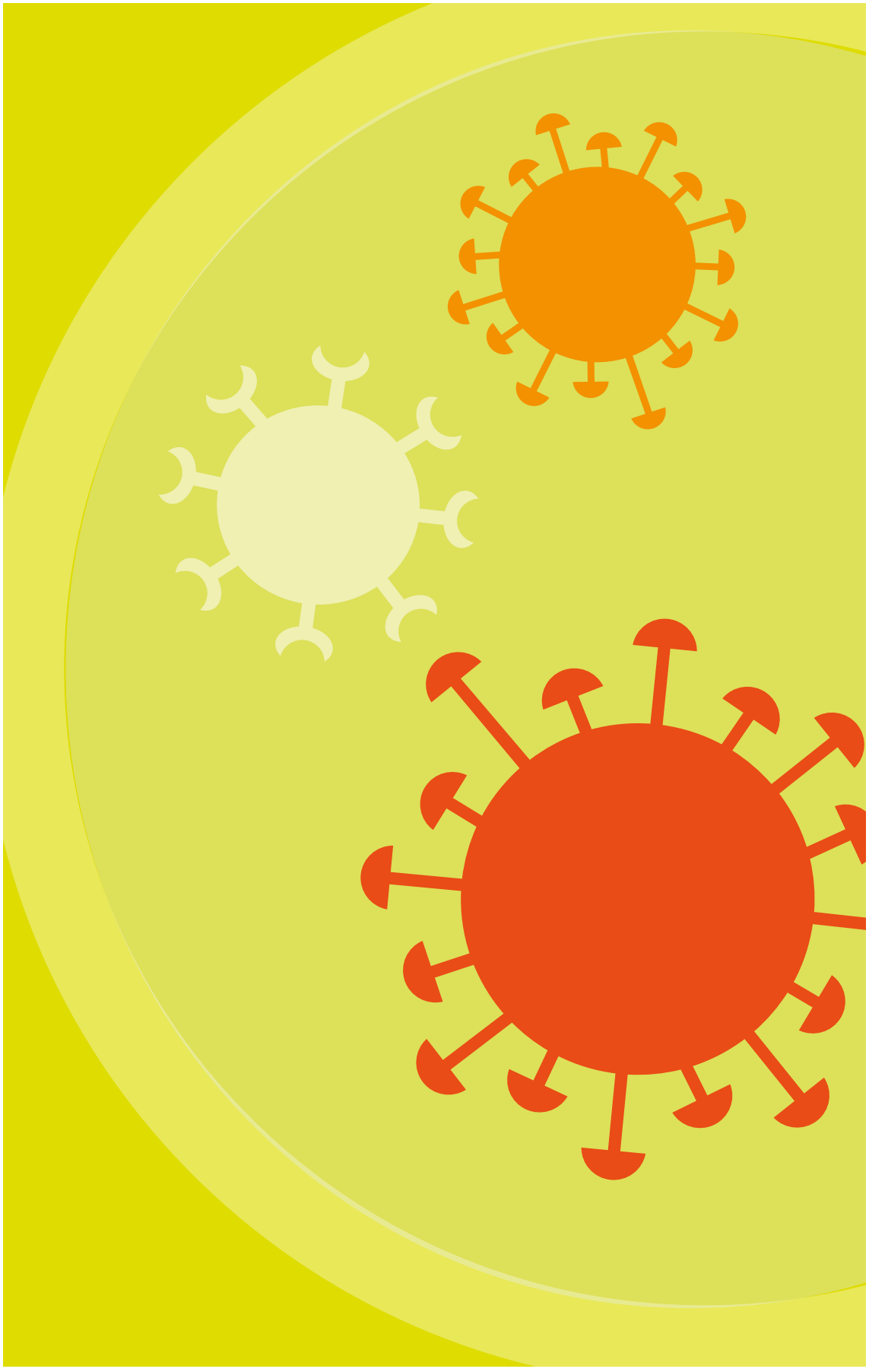
Cathomas R. et al. Intravesical recombinant BCG followed by perioperative chemo-immunotherapy for patients with muscle-invasive bladder cancer (MIBC). A multicenter, single arm phase 2 trial (SAKK 06/19).

Poster

Mark M. et al. SAKK 19/17 – Safety analysis of first-line durvalumab in patients with PD-L1 positive advanced NSCLC and a performance status of 2.

Poster

Ribi K. et al. Quality of life and pain in patients with metastatic bone disease from solid tumors treated with bone-targeted agents – a real-world cross-sectional study from Switzerland (SAKK 95/16).



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