Annual report 2021

SAKK
WE BRING PROGRESS TO CANCER CARE

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Prof. Dr. med. Roger von Moos,
SAKK President

Success consists of getting up just one more time than you fall

(Oliver Goldsmith)

Dear Readers,
Dear Colleagues,

Success consists of getting up just one more time than you fall (Oliver Goldsmith). It's with this saying in mind that I would like to present the Annual Report 2021. My second term as President of SAKK ends in December 2021, six years after I was elected.

I can look back on some wonderful times, but there were difficult times too.

We succeeded, for example, in adding a further three sites – Biel, Solothurn and Claraspital – to the SAKK network. These hospitals filled gaps in an area in which very few SAKK trials had been performed, or added special expertise in specific disease entities. In addition to expanding the number of sites, a grant from the Cancer League was used to strengthen medium-sized sites in 2018. This program, which resulted in greater networking in the regions in which the member hospitals are based, was a great success. The research strategy was honed and SAKK moved into new fields. The Working Groups Molecular Oncology and Immuno-Oncology were created as new cross-sectional groups not focused on specific diseases. Later, the Working Group Cellular Therapies was set up, again with crucial support from the SAKK Coordinating Center (CC) and myself.

The growth strategy adopted by SAKK showed how powerful our network can be. In 2020 almost 2,000 patients were recruited into trials, more than ever before in the 56-year history of our Group; the figure in 2015 was 919. A reorganization of the strategic and operative levels was conceived and discussed with external guidance during the 2018 retreat, but unfortunately it was rejected by a large majority of the Board. A decades-old strategy for trial funding decreed that a trial should be started when a certain percentage of the total had been physically ac-

quired, with the aim of acquiring the remaining funding while the trial was ongoing. An increasing number of academic trials with a funding ratio of just 40 % were opened under this strategy, with the funding goal not being achieved during the trial period.

Combined with the sites' difficulty in recruiting fast enough, this resulted in a dramatic imbalance in our finances at the end of 2020. It was only the decisive intervention of the Executive Board under Martin Reist and some of the Board members led by myself that enabled us to change course. Martin Reist and I held numerous discussions with SAKK sponsors from industry, foundations, and the federal government, and we were gratified to receive support of a kind that can certainly not be taken for granted. I would particularly like to mention the State Secretariat for Education, Research and Innovation (SERI), which not only provided us with exemplary support but also gave us clear and helpful guidance on restructuring the organization. A core team comprising Sacha Rothschild and Richard Cathomas carried the restructuring forward, and a selection committee working with Bernhard Pestalozzi identified suitable candidates for the post of President. The new structures and bylaws were approved at the extraordinary General Assembly on September 8, 2021, and the new members of the Board and the Scientific Committee were elected on November 18, 2021. Intensive work at the CC in consultation with financial experts combined with major progress in IT enabled financial tools to be developed that are among the most modern in academic research and will prevent SAKK from running into financial difficulties again. This was confirmed in a review performed by the federal government. We can be proud of the fact that, thanks to the extreme efforts of all involved, and those at the CC in particular, SAKK is now financially sound and has a modern structure that minimizes potential conflicts.

It was necessary to ward off many attacks from within the ranks of our members during this difficult period. I can fully understand their frustration and disappointment. I am particularly sorry that more than 25 jobs were lost at the Coordinating Center, through absolutely no fault of those concerned, in order to save the organization. It is of course also regrettable that ultimately some trials still had to be closed, although the outcome here was much better than initially anticipated.

Ask not what SAKK can do for you – ask what you can do for SAKK

(adapted from John F. Kennedy)

I would like to take this opportunity to sincerely thank everyone who supported our institution during this difficult time and whose commitment helped to achieve the turnaround. My particular thanks go to our CEO Martin Reist. Without his superhuman and inexhaustible efforts we would never have been able to reach this turning point in such a short time.

I would like to ask everyone else to show the new SAKK the trust that it deserves. It is time for the period of accusations and fault-finding to end. Come back on board, help to get the boat moving; we need to function as a network and as a team in order to derive the maximum benefit from clinical research in Switzerland for our patients with hemato-oncological diseases. In my role as Past President of SAKK I will do whatever I can to support the Group on its way into the future.

Prof. Dr. med.
Roger von Moos
SAKK President

Clinical research for the benefit of our cancer patients is and will remain the central task of SAKK.

Prof. Dr. med. Miklos Pless

Interview with Prof. Dr. med. Miklos Pless, SAKK President as from 1.1.2022

You have been on the SAKK Board for eleven years now. What is the main thing that has changed now that you have been elected President?

There are many things. You have to remember that all our structures are completely new, as are many members of the Board and the entire Scientific Committee. It is only now that I am realizing the scope and variety of the challenges and tasks that the President has to deal with. All my predecessors deserve my sincere respect! Fortunately, there is great solidarity among all the Board members, and the assistance and experience provided by the Coordinating Center and the CEO are without precedent in this situation.

In the future the composition of the Board will be more diverse. It will also include members from outside the SAKK network. How do you envisage cooperation with your new colleagues?

That will be both a challenge and a real gain. It will be a challenge, for example, because we oncologists generally like to avoid conflict, and politicians are the opposite: they address differences more directly. We'll need to get used to working together on this score. Above all, though, it will be a gain because we will enhance our competence with respect to public health policy, finances, and political support. This broadening will most definitely make SAKK stronger.

Switzerland currently has no cancer strategy; the National Strategy against Cancer (NSC) ended in 2020. Coordination between the cancer organizations takes place without the involvement of the federal government or cantons. Shouldn't an effort be made to once again involve all the stakeholders in order to overcome the complex challenges associated with the battle against cancer?

Our work is naturally continuing with no less urgency even though the NSC has ended. The NSC brought together many important players in oncology, and addressed a very wide range of tasks. This major achievement must not be wasted. It would of course be very welcome if the political bodies were to get involved again, in terms of both content and funding. Clinical research for the benefit of our cancer patients is and will remain the central task of SAKK; we will do our utmost to perform this task well – no, excellently!

SAKK is an important platform that networks researchers, physicians, and patients. Where do you see SAKK in three years?

We will continue to expand our core activity – clinical trials – but will also become more open to modern developments. Big data, registry with real-world data, cellular therapies – these are all initiatives that have recently emerged, and they need to become established over the next few years.

We will also continue to adapt our structures to make SAKK attractive, reliable, and successful for our members, employees at the Coordinating Center and, above all, patients. The reorganization was the first step in this process. We are planning an initial evaluation of these structures in one to two years, along with any necessary improvements.

And finally, we need to motivate young academic talents, and women in particular, to get involved in SAKK. The Young Oncology Academy serves this purpose, and this is something that can be further expanded. It is gratifying to see that a real generational change has taken place in the Scientific Committee: the members are all new and younger colleagues, and they represent a large number of important members, among them the universities.

I am confident that in three years we will be in a very good position financially, scientifically and with respect to the individuals involved.

January-February

GU Cancer Forums in Zurich, Lausanne and Ticino
January 9, January 28, and February 24, virtual

The GU Cancer Forums organized by SAKK provide the medical community in Switzerland with a platform to present the highlights from international uro-oncology congresses (ASCO GU, EAU, AUA, ASCO, ESMO and ASTRO). The format of the events was well received, as shown by the number of participants (between 70 and 92) and speakers (between 4 and 18).

May

SAKK May Semi-Annual Meeting
May 5–7, virtual

Our SAKK project groups, working groups, and sections meet at the SAKK semi-annual meetings to discuss and elaborate proposals for trials. The semi-annual event also offers various training and continuing education opportunities for investigators, study coordinators, and other health care professionals working in clinical research. In addition to scientific symposiums on recent trends in oncology, the SAKK Patient Advisory Board hosted an event specifically for patients, their families, and the general public.

COVID-19 and cancer:
The latest research findings for patients
May 6, virtual

The SAKK Patient Advisory Board hosted a patient forum featuring a series of lectures on May 6 to tie in with the SAKK Semi-Annual Meeting. More than 50 people took part in the free event, at which they heard about findings from research into COVID-19 and cancer presented by renowned experts in oncology and infectious diseases. After the lectures the participants took the opportunity to ask the speakers many questions, highlighting further interesting aspects of the pandemic and cancer.

St. Claraspital is a new member of SAKK

We are delighted to welcome St. Claraspital as a new regular member of the SAKK network. Prof. Dr. med. Dieter Köberle and PD Dr. med. Arnoud Templeton explained their motivation to become a member of SAKK, and were elected with an overwhelming majority at the SAKK General Assembly in May 2021. The SAKK General Assembly now comprises 20 members with voting rights.

1st Swiss PostAACR
May 6, virtual

This year, SAKK organized the 1st Swiss PostAACR in collaboration with Oncoviews. The Scientific Committee presented a selection of highlights from AACR 2021, the Annual Meeting of the American Association for Cancer Research, to the online participants. Over two hours, five renowned physicians – who attended the event in Bern in person – presented key elements of their research projects, which offer extremely promising findings for cancer patients. Even though we were organizing the PostAACR for the very first time, we nonetheless attracted a total of 100 participants from 16 countries! We would like to thank you for the fascinating discussions and valuable dialog.

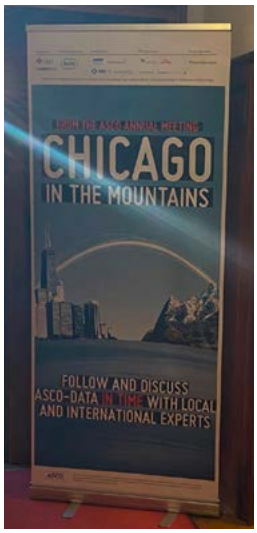
Germline genetic testing and genetic counseling for prostate cancer patients in daily clinical practice
May 26, webinar

SAKK organized a series of lectures by renowned experts and discussions on the topic of Current guidelines and treatment options for patients with pathogenic variants and alterations in DNA repair genes.

June

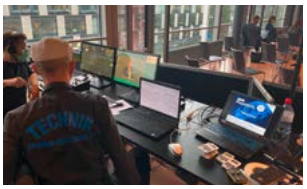
Chicago in the Mountains
June 10–12, Flüeli-Ranft and virtual

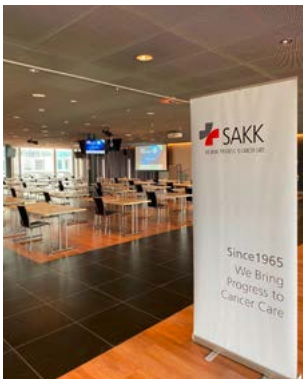
The well-established Chicago in the Mountains Meeting once again took place in the historic Hotel Paxmontana in Flüeli-Ranft. Key content from five sections (Breast/Gyn, GI, GU, Lung and Varia) of the scientific program of the annual meeting of the American Society of Clinical Oncology (ASCO) was presented and discussed by experts. Some 100 participants who attended in person or online were very appreciative of the opportunity for personal interaction and the valuable discussions of the practice-changing ASCO content.



15th Swiss PostASCO
June 24, Bern

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 event was held with some 50 participants at the Wankdorf Stadium in Bern in compliance with COVID safety guidelines. Nationally renowned speakers, experts, and young scientists presented the data from the ASCO21 Meeting along with their interpretation. The audience of specialists appreciated the opportunity to participate actively and on-site in the discussions. The webcasts were made available to all interested parties after the event.





8th Introductory Course in Genetic Counseling in Oncology
June 25-26, St.Gallen

This official SAKK postgraduate training event is organized every year by SAKK under the auspices of the CPTC network (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.

September

"Writing scientific publications" seminar
September 2–3, Winterthur

Cantonal Hospital Winterthur offers this two-day seminar in conjunction with SAKK; it teaches the principles of writing a good scientific publication. Once again, the seminar was fully booked very early on.

9th Introductory Course in Genetic Counseling in Oncology
September 3–4, Lausanne

The introductory course in genetic counseling in oncology has been successfully running for years in St.Gallen; in 2021 it was additionally offered in Lausanne for the first time.

SAKK Translational Urogenital Cancer Network Meeting & Award
September 9–10, Zurich

This event primarily addresses young researchers in clinical and translational research. Here SAKK provides a platform designed to intensify the dialog between these two types of research and to promote collaboration. This year's meeting was attended by 25 participants. Prof. Dr. med. Andrea Alimonti from the IOR Institute of Oncology Re-

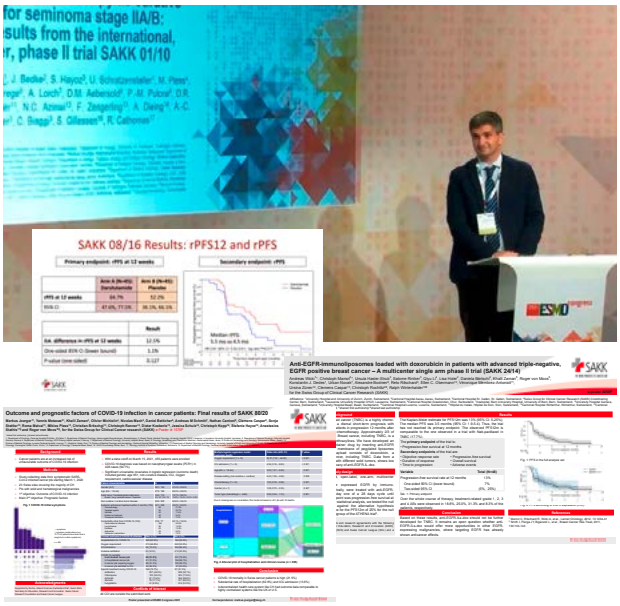
search in Bellinzona kicked off the event with a keynote lecture on "Targeting MDSCs for prostate cancer therapy." The following day, six young researchers presented work from their research areas.

The 1st SAKK Translational Urogenital Cancer Meeting Award went to Dr. Ilaria Guccini from ETH Zurich for her paper on "Senescence Reprogramming by TIMP1 Deficiency Promotes Prostate Cancer Metastasis."

Race for Life
September 12, Bern
SAKK took part in the Race for Life charity bicycle marathon and solidarity festival for the fifth time. It was represented by two teams that rode a total of 1,122 km! SAKK Race Team 1 took 1st place after completing 756 km – congratulations! SAKK Race Team 2 took 5th place with 366 km – thank you all for such a great performance! The cyclists' efforts were rewarded with donations that benefited cancer patients and promoted cancer research.

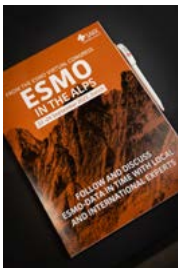
SAKK Presentations at the ESMO Congress
The following SAKK trials were presented at the Annual Congress of the European Society for Medical Oncology (ESMO) from September 16–21, 2021:

- *ePoster:* Jörger M. et al, SAKK 80/20: Outcome and prognostic factors of COVID-19 infection in cancer patients: Final results of SAKK 80/20.
- *ePoster:* Wicki A. et al, SAKK 24/14: Anti-EGFR-immunoliposomes loaded with doxorubicin in patients with advanced triple negative, EGFR positive breast cancer – A multicenter single arm phase II trial [SAKK 24/14].
- *Oral presentation* (Mini oral): Cathomas R. et al, SAKK 08/16: Darolutamide maintenance in metastatic castration resistant prostate cancer (mCRPC) previously treated with novel hormonal agents (NHA) and non-progressive disease after subsequent treatment with a taxane: A randomized double-blind placebo-controlled phase II trial (SAKK 08/16).
- *Oral presentation* (Proffered paper session): Papachristofilou A. et al, SAKK 01/10: Single-dose carboplatin followed by involved-node radiotherapy as curative treatment for seminoma stage IIA/B: efficacy results from the international multicenter phase II trial SAKK 01/10.



ESMO in the Alps
September 22–24, Zurich and virtual

SAKK organized ESMO in the Alps, a meeting parallel to the ESMO Congress 2021, for the second time. It presented a selection of highlights to a live and online audience. Around 60 people in total took part in the hybrid format. The Scientific Committee selected recent key findings in six categories, and these were discussed with experts. The webcasts were made available to all interested parties after the event.



November

SAKK November Semi-Annual Meeting at the SOHC
November 18–20, Zurich

The SAKK winter semi-annual meeting took place at The Circle at Zurich airport, tying in with the 4th 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.

SAKK/SCTO Discussion Round:
Lay Summaries of Clinical Trial Results
November 20, Zurich

The SAKK Patient Advisory Board organized an event on the topic of "Lay Summary of Clinical Trial Results" to tie in with the SOHC Congress, at which representatives of patient groups, researchers, Swiss authorities, and clinical trial sponsors met to discuss this subject and share experience.

Prize Awards at the SAKK Winter Semi-Annual Meeting

The following prizes were awarded at the SAKK Winter Semi-Annual Meeting during the SOHC Congress:

SAKK/Amgen Research Grant

was awarded to Prof. Dr. med. et rer nat. Markus Jörger from Cantonal Hospital St.Gallen for the project "SAKK 96/12 Substudy Bone Turnover Markers in patients Receiving 4-Weekly versus 12-Weekly Denosumab in the SAKK 96/12 Randomized-Non-Inferiority Phase III Trial. A Prospective Kinetic-Pharmacodynamic (K-PD) Population Modeling." This research prize is awarded to promote translational research in Switzerland. It honors new and exceptional projects that help to improve the lives of cancer patients.

SAKK/Astellas GU-Oncology Award

was awarded to Dr. med. Clémentine Le Magnen from University Hospital Basel for the project "A comprehensive study of prostate cancer patient-derived organoids." The SAKK/Astellas GU-Oncology Award focuses on specific improvements in patient management and the results of treatment for urogenital cancers. The prize worth CHF 30,000 seeks to support continuing research activities. The research group must therefore use the prize money for ongoing and future research work as part of the research project.

SAKK/BMS Grant "HEM Pioneer"

was awarded to Dr. med. Noémie Lang from Geneva University Hospitals (HUG) for the project "Swiss PTLD: Liquid biopsy-based genomic assay to enable non-invasive precision diagnostics and monitoring of post-transplant lymphoproliferative disorders (PTLD)."SAKK's"HEM Pioneer Grant" is sponsored by BMS and is intended to support projects with the potential to pave the way to a fundamental change in the therapy of leukemia. The grant is endowed with CHF 50,000.

SAKK/Dr. Paul Janssen Fellowship
was awarded to Dr. med. Franziska Siegenthaler from University Cancer Center Inselspital (UCI) – Das Tumorzentrum Bern. Endowed with CHF 30,000, the purpose of this research grant 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.

SAKK/Novartis: Together for Patients Award
was awarded to Dr. med. Wiebke Rösler from University Hospital Zurich for the project "The SWISS HISTIOCYTOSIS REGISTRY – a comprehensive platform for health care research, translational research and patient support." The award is endowed with CHF 30,000 and encourages innovative patient-focused projects in oncology and hematology.

SAKK/Pfizer Award
was awarded to Dr. med. Florentia Dimitriou for the project "Anti-PD-1 alone or combined with ipilimumab in patients with mucosal melanoma: a multicentre, retrospective, cohort study." This prize, awarded for patient-oriented, practical clinical cancer research, is endowed with CHF 20,000. The paper may not be more than a year old at the time the prize is awarded, and it must include specific proposals for improving the treatment and the therapeutic results that are achievable in cancer patients.

Young Oncology Academy 2021

The SAKK Young Oncology Academy was organized for the fifth time in 2021. Ten young doctors benefited from this annual SAKK support and mentoring program, taking part in postgraduate training events, continuing education at phase I sites, and courses on writing presentations and medical papers. The emphasis was particularly on giving the talented young scientists insight into the successful development, management, implementation, and publication of a clinical trial. A participant working in surgery and one working in pathology attended the Young Oncology Academy for the first time; we were also delighted to welcome an international mentee from Greece to the program. During the program, the mentees produced the review papers "Highlights of EHA, ESTRO, ESMO & ASCO," which were presented to an audience of experts at the SAKK Winter Semi-Annual Meeting.

December

2nd SAKK SMASH

December 16–17, virtual and live at Schloss Hünigen

For the second time, SAKK organized this popular postgraduate training event for both specialists and physicians in office practice in Switzerland. SMASH (**S**AKK **M**eets the hemato-oncological abstracts of **ASH**) gave around 80 participants the opportunity to review and discuss a selection of abstract presentations from the Annual Meeting of ASH (American Society of Hematology) with twelve nationally acclaimed experts.

Highlights of the SAKK Research Groups

Project Group Breast Cancer

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

After a successful 2020 in which the Project Group Breast Cancer managed to enroll 565 patients in interventional clinical trials, 2021 proved to be a very difficult year. In 2021, we only accrued 80 patients (76 patients in interventional trials and four patients in database studies). The reason for this lower performance was the suspension of all our proprietary SAKK trials in the context of SAKK's crisis. One trial even had to be closed down completely. Therefore, for the majority of the year, only intergroup trials were open for accrual.

We accrued 13 patients in **IBCSG trials** (seven patients in IBCSG 55-17 TOUCH, which investigates a chemotherapy-free regimen in postmenopausal patients with early HER2-positive breast cancer, and six patients in IBCSG 59-19 POLAR, which looks at adjuvant palbociclib in patients with a resected loco-regional relapse).

The **TAXIS trial (SAKK 23/16, European Axilla Study)** had to be suspended. This large surgical phase III trial with 1,500 patients will answer the question of whether tailored axillary surgery in clinically node-positive breast cancer is non-inferior to a conventional axillary dissection. Thanks to the considerable, tireless efforts of the principal investigator, the sponsorship of this trial was able to be transferred under the umbrella of the Oncoplastic Breast Consortium (OPBC) in Basel with the new name OPBC-03/SAKK 23/16/IBCSG 57-18/ABCSG-53/GBG 101 and was reopened for accrual in May 2021. Since then, 54 Swiss patients and 13 foreign patients have been randomized. The cumulative accrual is now 458 patients, including 287 from our group.

The **REDUSE trial (SAKK 96/12)** also had to be suspended. This large phase-III non-inferiority trial with 1,380 patients investigates the optimal dosing of denosumab in bone metastasis. In relentless negotiations with Swiss insurance companies, the principal investigator secured the funding needed to reopen this important trial. Since its reopening in November 2021, nine patients have been accrued by our group.

The **VISION I trial (SAKK 23/18)** was also suspended. This trial investigates patients after neoadjuvant chemotherapy with complete remission (confirmed by imaging) to see whether residual microscopic disease can be detected with sufficient sensitivity by means of biopsies. If this trial reaches its endpoint, it will serve as the basis for a further generation of trials that will aim to treat patients with complete remission after neoadjuvant chemotherapy without surgery. The principal investigator is working hard on a sponsor transfer, and it is expected that SAKK sites will be able to accrue patients again in 2022.

In addition to these interventional trials, our group accrued four patients in **SAKK 80/19 (AlpineTIR)**, an immuno-oncology database trial.

In 2021, there were six **publications** in peer-reviewed journals authored or co-authored by members from our group (one from SAKK 23/16, four from IBCSG trials, and one from a BIG trial). In addition, four members of our group were part of the St.Gallen Consensus Panel 2021 and two of them co-authored the St.Gallen Consensus Paper. We were present at the ESMO conference 2021 with two **posters:** SAKK 24/14 (Anti-EGFR-immunoliposomes loaded with doxorubicin in patients with advanced triple-negative EGFR positive breast cancer) and SAKK 80/20 (Outcome and prognostic factors of SARS-CoV-2 infection in cancer patients) with co-authors from our group.

For 2022, we are developing **two trials in the neoadjuvant setting** (one of them in collaboration with the Project Group Developmental Therapeutics) and one in the metastatic setting. Furthermore, several of our sites will participate in the upcoming phase III trial **IBCSG 65 DECRESCENDO.** This intergroup trial is investigating whether the intensity of adjuvant chemotherapy in HER2-positive breast cancer can be tailored according to the response to neoadjuvant chemotherapy. We are confident that these new opportunities, together with the reopening of our two major trials, will substantially raise the accrual performance of 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,
University Hospital Zurich
Dr. med. Dr. rer. nat. Christian Britschgi,
University Hospital Zurich

The SAKK Project Group Developmental Therapeutics (PG DT) was successfully launched in November 2019 as a merger of the former Project Group New Anticancer Treatments (NAT) and the Working Groups Immuno-Oncology (IO) and Molecular Oncology (MO). This restructuring allows us to make optimal use of the expertise of all members, to have strong trials in the immunotherapy and non-immunotherapy fields, potential combinations of the two fields, and strong translational programs. This will enable the PG DT to have a broadened focus on innovation in oncology as well as a larger member base. Until 2022, the PG DT will be led by the current President (M. Jörger) and vice president (A. Stathis) along with the vice presidents with a focus on immunotherapy (A. Curioni-Fontecedro) and molecular oncology (C. Britschgi) respectively.

After the restructuring of SAKK in early 2021, the PG DT was able to reactivate all ongoing clinical trials with the exception of SAKK 66/18, which is still in negotiation with both industry partners. In 2021, our group successfully launched three clinical trials: **SAKK 67/20** (PI Dr. med. Ilaria Colombo) is testing a new micellar docetaxel compound from Oasmia Pharmaceutica in patients with metastatic, castration-resistant prostate cancer. SAKK 67/20 successfully recruited the first patient cohort and is currently recruiting on the second dose level. **BASILEA CDI-CS-002** is a clinical trial that studies the colchicine site inhibitor lisavanbulin in patients with relapsing, EB1-positive glioblastoma. The trial is recruiting in the UK and Switzerland (within SAKK), and successfully established a broad EB1 screening program in glioblastoma patients undergoing initial surgery. **BAY 1895344** is an international trial testing the combination of pembrolizumab with the oral ATR-inhibitor BAY 1895344 (elimusertib). This trial builds on a successful collaboration between SAKK and Bayer in the elimusertib monotherapy trial that was successfully completed in 2021 (**SAKK 69/17**) and it recruited very well, even in comparison with international sites such as the Royal Marsden and the MD Anderson Cancer Center.

SAKK 66/17, a trial that combines tumor laser ablation with intratumoral injection of the new immune stimulatory compound IP-001 (Immunophotonics) successfully completed the initial safety phase and will reopen accrual in Q1 2022. Based on the successful collaboration between SAKK and Immunophotonics, a second SAKK-led international trial with the combination of radio-frequency ablation (RFA) and IP-001 in patients with advanced lung or colorectal cancer is set to open in mid-2022. **SAKK 65/16** involving the new liposomal doxorubicin compound TLD-1 or Talidox from Bern-based Innomedica finalized patient recruitment in the phase 1 part in Q1 2021 and is currently recruiting patients into the bioequivalence part (PK comparison with Caelyx). At the same time, a large randomized registration trial in patients with advanced breast cancer comparing TLD-1 with standard-of-care chemotherapy is currently in preparation. **SAKK 11/16** with the cell-based antitumor immunization MVXONCO-1 in patients with advanced head and neck cancer has been taken over by MaxiVax and has made successful progress, with accrual expected to be finalized in 2022.

The PG DT also finalized recruitment and even the final analysis of **SAKK 80/20** that studied roughly 450 cancer patients infected with COVID-19, and the publication will be submitted in Q1 2022.

During the course of 2022, the PG DT is expected to open a new trial on Intensity's **INT230-6**, a combined formulation of cisplatin, vinorelbine and a diffusion enhancer in patients with early-stage triple-negative breast cancer (TNBC). The concept has successfully been negotiated with Intensity Therapeutics and is supported by both the PG DT and the SAKK Project Group Breast Cancer. We expect the trial to be recommended by the Scientific Committee in February 2022 and be approved by the Board of Directors in March 2022, so that protocol development may begin promptly.

Project Group Gastrointestinal Cancer

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

In 2021 recruitment into the trial **SAKK 41/16** (RECAP), which is investigating the neoadjuvant use of regorafenib in colorectal cancer, was successfully completed. Congratulations to the PI, Dr. med. Sara Bastian, for bringing the trial to a successful conclusion despite the adverse circumstances (COVID). The RECAP trial once again illustrated SAKK's prowess in performing complex, early-stage trials in cancer patients. Two abstracts containing pharmacokinetic data from the trial have already been published.

The **DANTE trial,** which completed recruitment in 2020 under the leadership of the international PI Prof. Dr. med. Salah-Eddin Al-Batran and the national PI Dr. med. Alexander Siebenhüner, presented initial findings in two abstracts at ESMO 2021. We look forward to the forthcoming publication of the full trial.

In 2021, furthermore, **two articles were published** based on data from the trials SAKK 40/00 and SAKK 41/06, among others. Morarasu et al. investigated the outcome of high colorectal cancer and cancer of the rectosigmoid junction. These cancers had higher recurrence rates than more proximal colorectal cancers. Salvatore et al. investigated the role of bevacizumab in maintenance therapy of colorectal cancer. This systematic review is based to a relevant extent on data from the trial SAKK 41/06 under principal investigator Prof. Dr. med. Dieter Köberle. The meta-analysis shows a limited benefit of bevacizumab in this setting.

One of the new clinical trials about to start is a **TIL trial** (SAKK 88/20) in GI cancers with microsatellite instability. Prof. Dr. med. et Dr. phil. George Coukos is playing a major role in developing and progressing this trial. I sincerely hope that full funding of the trial will be achieved and that it can start in 2022. Other initiatives such as a registry for pancreatic cancer will also hopefully pick up speed next year – PD Dr. med. Sara De Dosso, who had the idea, is putting a lot of energy into this project. Dr. med. Thibaud Köessler remains extremely active in the SAKK GI group and is working on a pancreas-related project and a project involving liquid biopsy.

And finally, a new president of the SAKK PG GI will be elected in March 2022. I would be delighted to meet young, enthusiastic clinical researchers keen to lead the group and bring new momentum to it and its projects. I am confident that this resourceful and committed research group has a bright future ahead of it.

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 was in the activation phase. In 2021, the main challenge was to keep these trials open despite the critical conditions at SAKK. Thanks to innovative models of responsibility sharing between the SAKK Coordinating Center (CC) and dedicated sites, it became possible to reduce costs and thereby enable the continuation of these crucial trials.

HOVON 150 and **156** mark the transition from a "one size fits all" strategy towards a personalized concept in the context of curative HOVON trials for young fit AML patients. At the same time, they reflect the important position of the SAKK PG LEUK within this globally leading AML trial group. The SAKK/HOVON 150 protocol is open for first-line treatment of fit AML patients with a mutation in the IDH1 or IDH2 genes. The SAKK/HOVON 156 protocol is open 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 late 2022 for the remaining (triple-negative) AML patients; it will investigate the randomized addition of venetoclax to standard chemotherapy.

The **HOVON 155** protocol for first-line palliative therapy was activated during 2021, and it achieved its recruitment goal at the end of 2021. It investigated the randomized addition of midostaurin to standard treatment with decitabine in unfit AML of all subtypes. Altogether, these HOVON trials offer an attractive and comprehensive portfolio for first-line treatment of AML patients.

For patients with untreated CLL, the trial **CLL 13** has reached its intended recruitment target. At the end of 2021, its successor trial, the trial **CLL 17**, was also activated for SAKK patients. This trial offers ibrutinib-based first-line treatment to untreated CLL patients.

After closure of the MDS Registry (**SAKK 33/18 I-CARE**), there is currently no protocol open for MDS patients. Similarly, there is no active trial for CML patients, since the plans to participate in the TIPI trial were not successful. The group is hopeful that it will be able to activate an **ALL SAKK/GRAALL** successor protocol during 2022. Finally, the SCORED registry trial (SAKK 80/20_CaSA) stopped accrual during 2021.

Project Group Lung Cancer

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

SAKK Trials for Lung Cancer/Mesothelioma
In 2021 the SAKK Lung Cancer group was active particularly in the localized stages (NSCLC stage III, SCLC limited stage), NSCLC stage IV, and inoperable mesothelioma.

In NSCLC stage III, recruitment continued throughout Switzerland into **SAKK 16/18**, which opened in 2020 with Dr. med. Laetitia Mauti as principal investigator. As with the previous trial (SAKK 16/14), this is a trimodal treatment concept involving systemic therapy, radiotherapy, and surgery in the age of immunotherapy. SAKK 16/14 was published in the *Journal of Clinical Oncology* (IF 44) in 2021, with PD Dr. med. Dr. phil. nat. Sacha Rothschild as lead author – without doubt a major highlight in the group's year. Radiomics subprojects of the trial SAKK 16/00 resulted in three further **publications** (Drs. Denzler, Oliviera and Vuong in Br J Radiol, EJNMMI Research and Sci Rep). In addition, a pooled analysis of various SAKK 16- trials which looked at specific surgical questions was the subject of an oral presentation by Prof. Dr. med. Isabelle Schmitt-Opitz at the AATS.

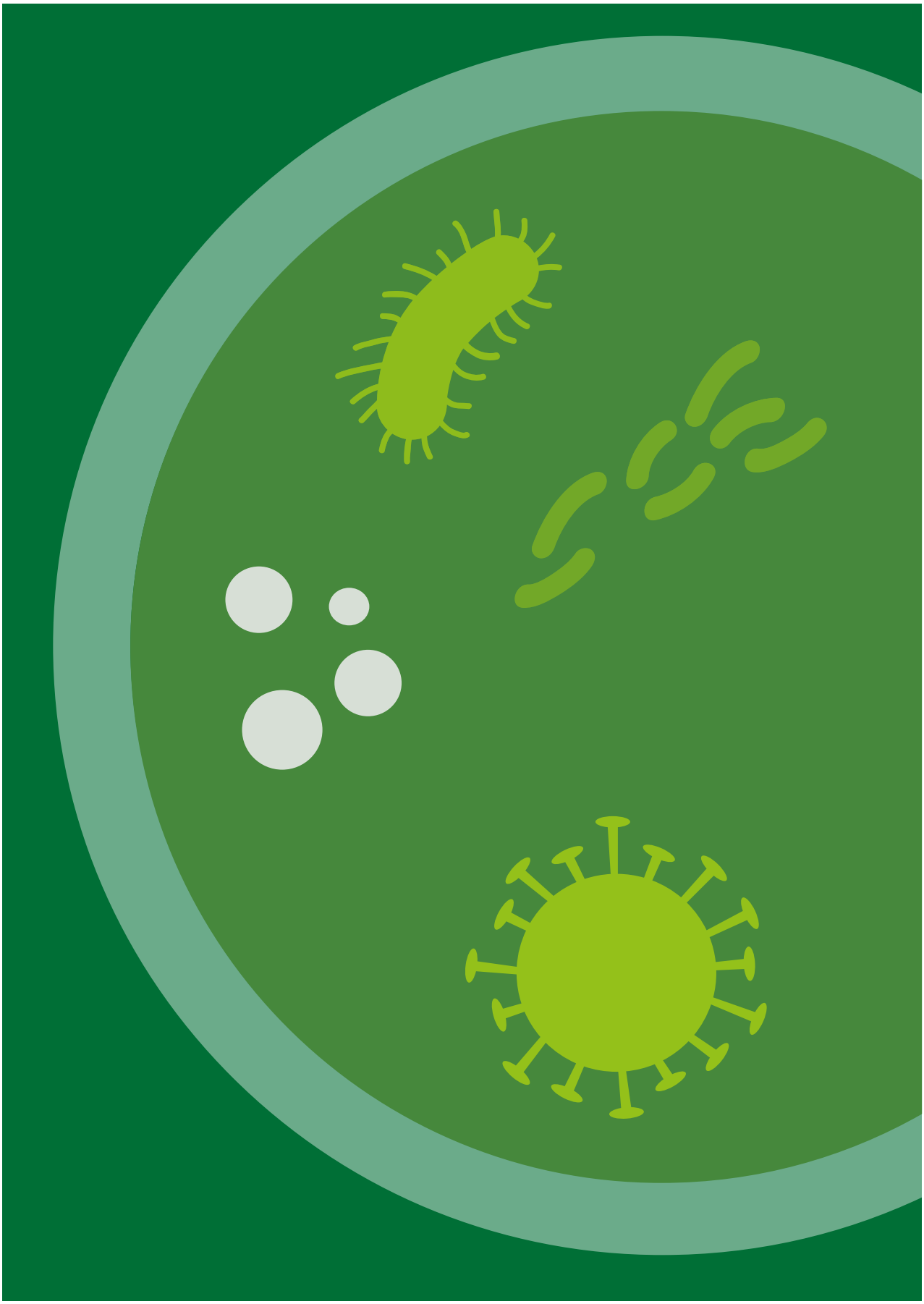
The objective of **SAKK 19/16**, a phase I trial in which two dose levels of the MEK inhibitor binimetinib were investigated in combination with first-line therapy with cisplatin and pemetrexed in patients with metastatic KRAS-mutated non-small cell lung cancer, was to establish the maximum tolerated dose. The trial was published in 2021 in *Lung Cancer* with Dr. Patrizia Frösch and Dr. Michael Mark as lead authors.

SAKK 19/17, a single-arm phase II trial run by Dr. Michael Mark in Chur with chemotherapy-naive NSCLC patients with PD-L1 positive tumors (>25 %) who are in poor general condition (PS2), recruited very rapidly in 2019. A safety analysis subsequently led to a temporary halt to recruitment. Dr. Michael Mark published the toxicity data in *Cancer Immunology, Immunotherapy* as an interim analysis in 2020, and recruitment will be complete once two more patients have been enrolled.

SAKK 15/19 is a trial for metastatic small cell lung cancer (SCLC) being run by Dr. med. Alfredo Addeo. This first-line trial will further investigate the value of chest radiotherapy in metastatic SCLC in the age of first-line chemoimmunotherapy. The trial is currently recruiting at various SAKK sites in Switzerland.

In the age of targeted therapies, in 2019 the group successfully initiated the phase II trial **SAKK 19/18** in patients with previously treated squamous cell carcinoma and FGFR mRNA overexpression. The oral FGFR inhibitor rogaratinib was investigated in this selected group in patients with no alternative standard therapeutic options. Recruitment was terminated after a total of 18 patients had been enrolled due to insufficient efficacy. Dr. med. Alfredo Addeo was, however, able to present the results as a poster at ASCO 2021, and the manuscript will be submitted to a journal in the near future.

PD Dr. med. Alessandra Curioni-Fontecedro at University Hospital Zurich led the ORIGIN trial (**SAKK 19/18**), recruiting patients with mesothelioma and metastatic NSCLC with progression after chemotherapy and immunotherapy. The trial is investigating the combination of gemcitabine



and atezolizumab, and the cohort of patients with lung cancer was achieved very rapidly. The trial is currently still open to patients with mesothelioma.

Collaborative Trials on Thoracic Cancers
Successful collaboration with the European Thoracic Oncology Platform (ETOP) continued in 2021. This collaboration is ongoing mainly in the context of major phase III trials and in niche trials for rare indications.

ETOP 13-18 BEAT-meso (a randomized phase III trial with chemotherapy and bevacizumab plus/minus atezolizumab in mesothelioma), a follow-up to the ETOP PROMISE trial which is recruiting very successfully, has almost reached its recruitment target. Recruitment was suspended briefly in 2021 when the primary endpoint was changed to overall survival. Recruitment at the SAKK sites was very good in comparison with the international sites, and the results of this trial have the potential to change the standard therapy.

ETOP 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 the *Journal of Thoracic Oncology.* It showed that denosumab had no effect. The trial was analyzed again in 2021 in a pooled study with the AMG 249 trial. This analysis again showed that denosumab offered no benefit (Prof. Dr. med. Solange Peters, Lung Cancer, 2021).

Furthermore, the results of **ETOP BOOSTER**, a randomized phase II trial to investigate the role of bevacizumab and osimertinib in patients with a confirmed T790M mutation and prior first- or second-generation EGFR tyrosine kinase inhibitor therapy, were presented at the plenary session of ESMO 2021 and subsequently published in *Annals of Oncology.*

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 this trial showed that postoperative radiotherapy for operated N2-positive NSCLC did NOT confer a survival advantage. The results were published in the January 2022 issue of *The Lancet Oncology.*

Recruitment into the **ACHILLES** trial in collaboration with the Scandinavian trial group was completed successfully in 2021, with a total of 20 patients enrolled at SAKK sites. This randomized trial will investigate the value of additive atezolizumab following completion of definitive radiochemotherapy in a curative setting in localized SCLC.

2021 was a successful year on the whole for the SAKK Project Group Lung Cancer, with a large number of publications and presentations and both newly activated and completed clinical trials. A very ambitious multinational project is planned for 2022. Led by Dr. Patrizia Frösch, it will investigate first-line therapy in patients with metastatic, PD-L1 high-expressing NSCLC, with targeted use of immunotherapy guided by ctDNA.

Project Group Lymphoma

President: Prof. Dr. med. Urban Novak,
Inselspital Bern (University Hospital of Bern), University of Bern
Vice president: Prof. Dr. med. Francesco Bertoni,
Institute of Oncology Research, Faculty of Biomedical Sciences,
USI, Bellinzona

In 2021 our group included 26 patients in a total of six clinical and interventional trials, and two more in the SCORED registry SAKK 80/19_AlpineTIR. These numbers are considerably lower compared to 2020, during which our group included a very high total number of patients (n = 249) in both clinical and registry trials. The significant decline cannot be fully attributed to the SAKK financial crisis of November 2020. With the exception of diffuse large B-cell lymphoma (DLBCL), we are lacking trials for our patients affected by the most frequent diseases, such as follicular lymphoma and multiple myeloma. For Hodgkin lymphoma, we are currently limited to the elderly population – which is small and difficult to treat – which receives BrECADD in an added cohort to the HD21 protocol.

It was therefore of decisive importance for our group that we finally launched **SAKK 38/19** in summer 2021. The design of the trial condenses the most up-to-date knowledge on the front-line therapy of DLBCL: as a proof of concept, circulating tumor DNA is incorporated in a prospective setting, and the second-generation BTK inhibitor

acalabrutinib is given only to the subset of DLBCL patients bearing specific genetic lesions that might benefit from this drug rather than the population as a whole. To pave the way for this flagship trial of our group, the acceptance of R-CHOP as the standard regimen was obtained in the 2018 SSH/SSMO Swiss consensus in lymphoma meeting during the SOHC congress and will hopefully survive current and future challenges in this field.

The phase I trial **SAKK 66/18** exploring the combination of copanlisib and venetoclax in relapsed/refractory B-cell lymphoma patients, co-run with the Project Group Developmental Therapeutics, was recruiting well in the year 2020. However, since then the trial has been on hold as we await feedback from the supporting pharmaceutical companies regarding the budget changes required by the financial restructuring at SAKK.

Unfortunately, HOVON decided to close its very important academic trial **HOVON 127/SAKK 37/16**, comparing the European versus the American standard treatment of Burkitt's lymphoma. With a total of 20 patients, the SAKK sites were among the best recruiters. Despite that, the global accrual rate was much slower than planned, mainly due to the lack of participation of UK sites.

Once again, the scientific output of the group remained outstanding in 2021, with four **publications** in Lancet journals on analyses in the framework of the Hodgkin trials HD14 and HD18 and the primary data of HD17, the publication of the results of IELSG 42, and two secondary analyses on the use and value of PET-CT as part of our trial SAKK 38/07 on the front-line therapy of DLBCL. Results of SAKK trials were **presented orally** (primary results of SAKK 36/13; secondary results of SAKK 38/07) during the 2021 International Conference on Malignant Lymphoma (ICML) in Lugano and at the 18th International Myeloma Workshop (SAKK 39/16 with its innovative design).

In November 2021, the group elected Prof. Dr. med. Francesco Bertoni as its new president and Prof. Dr. med. Thorsten Zenz as its new vice president. Let's support their work and the group's success through our continued commitment to currently recruiting and future trials! In this challenging transition phase for SAKK with many new colleagues in the various new structures of SAKK, we must be ready to provide thorough and critical analyses during the course of our work. Our financial sources must be diverse, and our commitment to truly independent clinical research must be firm. Our trial portfolio must be broad and appealing, and both relevant and realistic for the patients we have. It should be driven by quality rather than quantity and incorporate the innovations available in Switzerland. Finally, it will be of utmost importance to motivate young investigators to participate in our activities.

Project Group Urogenital Tumors

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

2021 was in many respects a successful research year for the Project Group Urogenital Tumors (SAKK PG URO), despite the difficult circumstances.

Recruitment was successfully completed for the following trials:

- **SAKK 08/14:** A total of 169 patients were recruited into this first-line mCRPC trial. The primary endpoint will be reached in 2022, hopefully followed by a presentation of the results soon after.
- **SAKK 07/17:** A total of 74 patients with advanced renal cell carcinoma were recruited into this trial. It may be possible to present initial results as early as 2022.

The difficult financial situation in which SAKK found itself led to the closure of several projects in the SAKK PG URO (SAKK 08/15, SAKK 09/18, SAKK 63/12, PEACE-4). Few projects are currently open for accrual:

- **SAKK 01/18:** Recruitment is going well for this stage IIA/B seminoma trial; 64 patients have been enrolled and treated.
- **SAKK 96/12:** This major trial was reopened towards the end of the year. Almost 200 patients still need to be recruited to reach the recruitment target of 1,300.
- SAKK 80/19 AlpineTIR: This registry trial also recruited successfully, with a total of 33 patients at the end of 2021.

The 2nd SAKK Translational Urogenital Cancer Network Meeting took place in Zurich in early September. Prof. Andrea Alimonti gave a superb keynote lecture with insights into his research on the gut microbiome. Nine projects were presented and discussed by researchers on the second day. Dr. Ilaria Guccini was awarded the prize for translational research, endowed with CHF 20,000, for her paper titled "Senescence Reprogramming by TIMP1 Deficiency Promotes Prostate Cancer Metastasis."

Among the **presentations and publications**, two contributions and oral presentations at ESMO 2021 deserve a special mention:

- **SAKK 01/10:** Presented by Dr. med. Alexandros Papachristofilou: Single-dose carboplatin followed by involved-node radiotherapy in seminoma stage IIA/B: efficacy results from the international, phase II trial SAKK 01/10
- **SAKK 08/16:** Presented by PD Dr. med. Richard Cathomas: Darolutamide 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 (SAKK 08/16).

The SAKK PG URO has several projects at the planning and preparatory stage, and it hopes that it will be possible to expand the portfolio again in the next year or two. The creation of a Core Group Team is also in preparation. It will be constituted at the next meeting in March, and one of its tasks will be to define a strategy for the SAKK PG URO for the next three years.

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 Sergio Zeerleder,
Inselspital Bern (University Hospital of Bern)

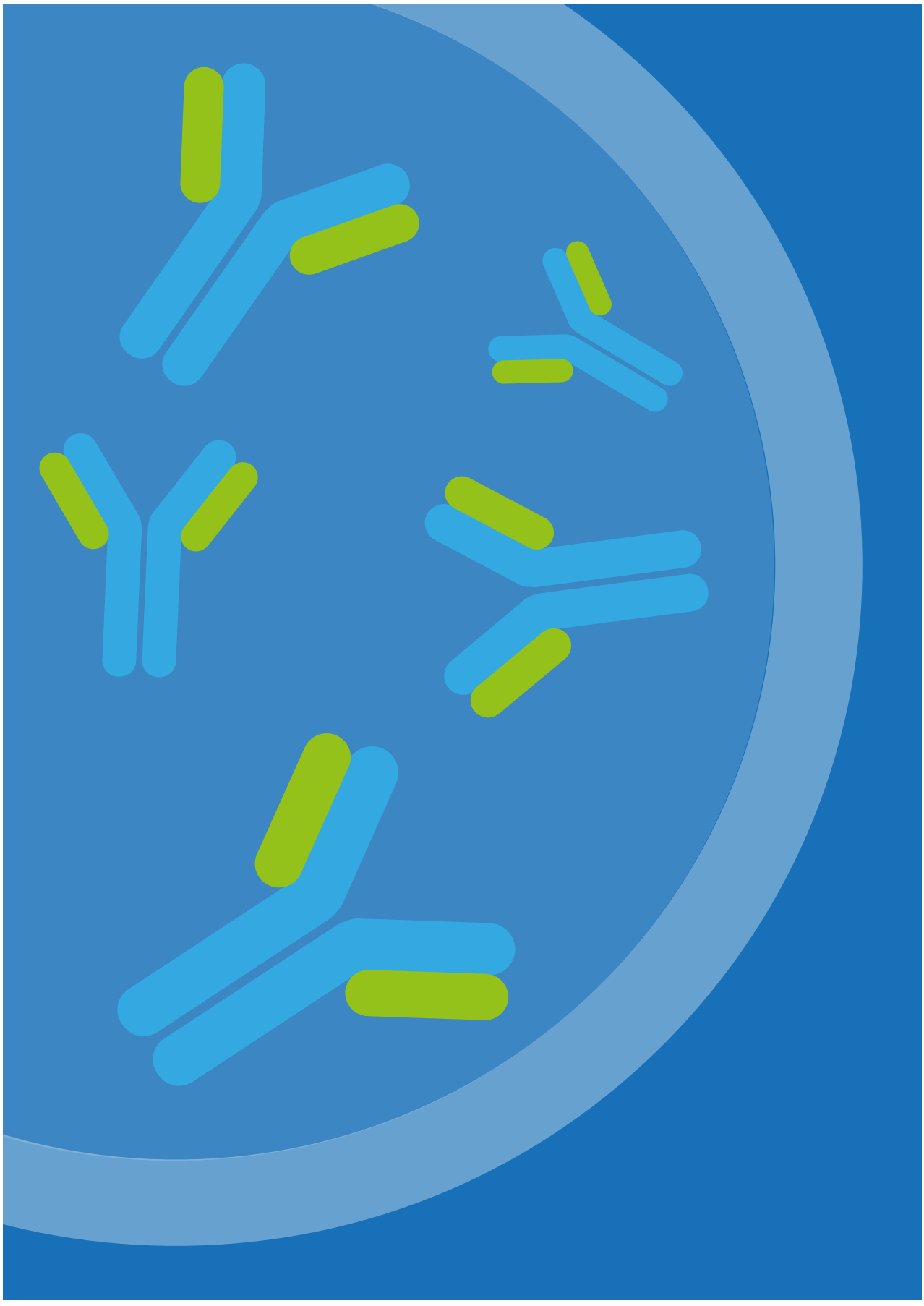
The core team met on a monthly basis and worked together enthusiastically to move cell-based technologies in Switzerland rapidly forward, developing a framework of goals, processes, and milestones. A close collaboration with the Swiss Blood Stem Cells Transplantation (SBST) with the representative Caroline Arber Barth is in place.

The members of the entire working group met twice at the SAKK Semi-Annual Meeting in 2021. Alongside the exchange of information and lively discussions, interesting translational research projects were presented and evaluated in detail.

The interim report to Swiss Cancer Research (SCR) regarding the "Establishment of a Swiss network for cell-based immunotherapies in oncology" was submitted in May 2021. SCR approved the report and thus assured their further support to the establishment of a Swiss network for cellular therapies.

The development of the first SAKK Board-approved pilot trial, **NeoTIL-ACT** (a multicenter pilot trial to assess the feasibility, safety, and efficacy of adoptive transfer of autologous tumor-infiltrating lymphocytes enriched for tumor antigen specificity in GI MSI-HIGH), was launched. As cellular therapies are very expensive, a funding strategy was developed based on grants and partners, including the Rising Tide Foundation for Clinical Cancer Research (RTFCCR), as well as Swiss Cancer Research (SCR).

The Working Group Cellular Therapies voted in favor of further developing a second project on immune monitoring and biobanking post CAR-T cell therapy as proposed



by PD Dr. med. Antonia Maria Müller. The proposal was also presented to the Project Group Leukemia, who strongly support the project.

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. The discussions 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. Future decisions by the Federal Office of Public Health and Swissmedic on cost compensation for cellular therapies and patient hospital stays strongly depend on the successful launch and conduct of a first pilot trial within the Swiss network for cellular therapies.

In 2022 the aim is to open the first clinical trial in the Swiss network and to jointly start implementation of the first translational research projects. The main hurdles to advancing these innovative cellular therapies will remain the same, i.e. funding 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)

Many tumors in the central nervous system (CNS) remain a major therapeutic challenge in the field of clinical oncology. The Working Group CNS Tumors (WG CNS) comprises experts from various disciplines and aims at expanding and strengthening the neuro-oncological community in Switzerland in order to provide brain tumor patients access to the best possible treatment options including novel therapeutic concepts.

The members of the WG CNS developed a consensus manuscript on the management of adult patients with diffuse gliomas in Switzerland. In 2021, a similar group of authors published a manuscript defining a consensus and minimum requirements to determine the "fitness-to-drive" of glioblastoma patients (https://smw.ch/article/doi/smw.2021.20501).

Traditionally, CNS tumors have not been a major focus within SAKK. However, the members of the group continue to be very active on a national and international level. In 2021, clinical trials for brain tumor patients were available at several Swiss sites. The ongoing COVID-19 pandemic was associated with restrictions that limited meetings and personal interaction. Nevertheless, the members of the group ensured management of brain tumor patients in Switzerland at a high level, which included access to novel therapeutic options in clinical trials. The group is working on new trial protocols and initiatives hoping that they can be implemented within the SAKK network in the next few years.

Working Group Gynecological Cancer

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

The working group took part in the European and global consensus conferences in 2021, and participation in the European ENGOT trials resulted in greater visibility. Its involvement in the "European experts consensus on BRCA/homologous recombination deficiency testing in first-line ovarian cancer" and the "6th global GCIG Ovarian Cancer Consensus Conference on planning and harmonizing clinical trials" deserve a special mention. Both consensus conferences were published in the respected journal *Annals of Oncology,* with Prof. Dr. med. Viola Heinzelmann-Schwarz as the Swiss partner.

We continued successful recruitment into **ENGOT trials** (ENGOT-en7_AtTEnd, ENGOT-ov50_INNOVATE-3, ENGOT/Ovar2.29/AGO-OVAR, ENGOT/Expression VI) and, through the Swiss GO Trial Group, we opened the ENGOT/MATAO trial. Several studies were closed in 2021: ENGOT-en7_AtTEnd, ENGOT-ov50_INNOVATE-3 and ENGOT/Expression VI. Recruitment was opened for ENGOT/BOUQET, meaning that currently three trials are open for recruitment. Trials within the SAKK Working Group Gynecological Cancer are organized by SAKK and by the Swiss GO Trial Group to maximize the number of trials that can be offered.

Closed Trials:

ENGOT-en7/MaNGo/AtTEnd (principal investigator in Switzerland: Dr. med. Manuela Rabaglio-Poretti) is a trial to investigate the benefit of adjuvant administration of a checkpoint inhibitor in addition to standard therapy in endometrial cancer. Patients with endometrial cancer at the advanced FIGO stage III/IV with a residual tumor or recurrence were to be given paclitaxel and carboplatin with/without atezolizumab. International recruitment into this trial was rather slow. We recruited 19 patients, fewer than promised, largely because some sites were not recruiting at all but also because of internal discussions surrounding funding for the trial. The trial was closed prematurely by the SAKK Board because full funding had not been secured. It closed prematurely at the end of 2021 after the necessary sample size had been reached, and at that point Switzerland was the fourth-best recruiting country in Europe.

ENGOT-ov50/BGOG/INNOVATE-3 (principal investigator in Switzerland: Dr. med. Eleftherios Pierre Samartzis) is evaluating the effectiveness of tumor treating fields in combination with weekly taxol chemotherapy in patients with platinum resistance with a maximum of two lines of chemotherapy after initial platinum resistance. This trial had full cost coverage, and was able to remain open in Switzerland until its closure. Patients were recruited at four sites only: Bellinzona, Cantonal Hospital Frauenfeld, University Hospital Zurich, and University Hospital Basel. We enrolled 17 patients in total (Basel, Frauenfeld, Zurich), and were the eighth-best recruiting country worldwide. The trial closed at the end of 2021 after the required number of patients had been enrolled.

Open Trials:

ENGOT-ov34/AGO/Ovar2.29 (AGO-OVAR) (principal investigator in Switzerland: Prof. Dr. med. Christian Kurzeder)

This trial opened in 2021 following extensive preparatory work and several modifications of the trial protocol in response to growing evidence that PD-L1 should be included as a predictive factor. The trial is investigating the benefit of administering the checkpoint inhibitor atezolizumab in addition to a combination of bevacizumab and paclitaxel or Caelyx in patients with recurrent platinum-resistant ovarian cancer. So far we have recruited eight patients into this RCT III trial at just three of six open sites. Accordingly, we already acquired 50 % of the promised cases in the first year after opening.

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)

This year regrettably saw various logistical adjustments to the SAKK trials in the Working Group Head and Neck Cancer (WG HN). The MaxiVAX trial (**SAKK 11/16**) and the 'best of' trial (**SAKK 10/16**) are continuing to recruit, albeit outside of SAKK and with new sponsors. The Bern follow-up trial is also being run outside of SAKK with the involvement of various sites.

The future interdisciplinary exchange and the group's future strategy were discussed at a group meeting. Unfortunately, there have been few proposals for discussion in recent months. The WG HN is intended as a brainstorming group from which further projects can emerge.

Working Group Imaging in Diagnostic and Therapy Monitoring

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

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 radiooncology, 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. It is therefore often the method used to assess the response of a tumor to treatment.

Given the ongoing pandemic, all group meetings were again held as virtual meetings in 2021. One particular topic of discussion was how the working group can continue to be involved in clinical trials as part of the SAKK organization, and what ideas of its own it might contribute. This includes support and advice on radiology and nuclear medicine issues for multicenter trials, and maintaining availability to advise on imaging questions from other working groups. To this end it was agreed to produce guidance (in the form of white papers) on subjects such as staging protocols for imaging in clinical trials; work has started on the first paper and it will be presented in the near future.

Working Group Melanoma

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

Due to the major achievements and several approved therapeutic regimens in the melanoma field in recent years, the initiation of national phase I-II trials represents a challenge.

The trial **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) was put on hold in 2021 for several reasons, including issues with the stability/quality of the laser. The trial is expected to open for accrual in the next few months.

The group was able to include a total of 13 patients in the SCORED registries (SAKK 80/19 AlpineTIR).

Outlook

- Few sites in Switzerland perform active melanoma research. Widespread clinical activity during the COVID pandemic is challenging, but we hope to improve as the pandemic is brought under control
- The update of the Swiss Melanoma Guidelines will be actively discussed in 2022

Working Group Sarcoma

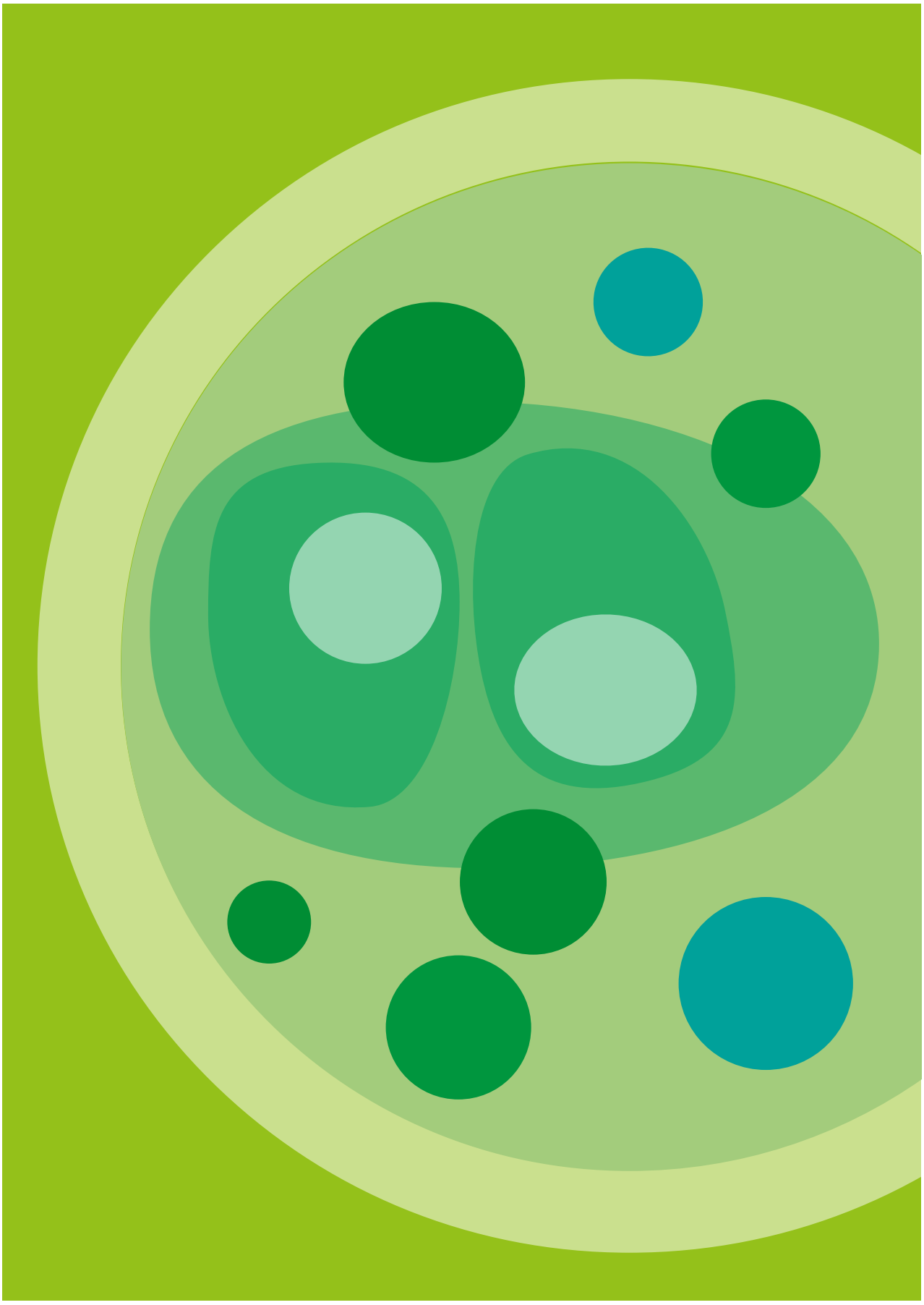
President: PD Dr. med. Attila Kollàr, Inselspital Bern

The highlights of the research year were the completion of the trial **SAKK 57/16** (NAPAGE trial), the analysis of its results and, in particular, the presentation of the trial findings at two major international sarcoma conferences, the CTOS (Connective Tissue Oncology Society) and the trinational sarcoma conference in Berlin. The trial shows that palliative chemotherapy in the form of nab-paclitaxel and gemcitabine is an active combination therapy for previously treated soft tissue sarcoma. Although the first attempt at soliciting interest from the pharmaceutical industry was unsuccessful, our group will do its utmost to realize the idea of a trial based on NAPAGE that would analyze the benefit and tolerance of the above combination therapy with an immunotherapy.

This year a great deal of effort went into evaluating participation in the **iEuroEwing** trial. This international, prospective, randomized phase III trial with principal investigator Prof. Dr. med. Uta Dirksen (Essen) is investigating several important questions relating to the optimal therapy, and maintenance drug therapy in particular, of patients with Ewing sarcoma. The application to the Ethics Committee was submitted. However, the funding of this trial – which is an academic one – still needs to be clarified before it can start.

The current collaboration with the Swiss Paediatric Oncology Group (SPOG) also deserves mention. Closer collaboration on sarcoma trials was discussed repeatedly in the past two years. This is because sarcomas occur both in children and in adults, and it is therefore not uncommon for sarcoma trials to enroll patients of all ages. Close and coordinated collaboration is accordingly not only desirable but of the utmost importance. Since the authorities will accept only one national sponsor for a clinical trial, our SAKK Working Group Sarcoma initiated an intensive, high priority discussion at presidential level which is still ongoing.

In the future, the SAKK Working Group Sarcoma will focus on initiating a new national sarcoma trial on the basis of success to date, and also on maintaining involvement in international trials.



Working Group Supportive Care and Palliative Cancer Care

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

The Working Group Supportive Care and Palliative Cancer Care is interested in any topic related to supportive and palliative care interventions, geriatric oncology, psycho-oncology, and cancer rehabilitation. Several trial proposals were discussed during 2021.

The **signal light trial** aims to investigate different methods of objective prognostication before tumor-directed palliative treatment. It was submitted to (and passed) the initial assessment of the Board as a piggyback trial in the call for elderly cancer patients for the Geriatric Oncology Therapy Optimization Program (GoTo program) of the Rising Tide Foundation for Clinical Cancer Research (RT-FCCR). Therefore, the assessment also needs to include a geriatric screening (G-8) together with two signal measures: a dynamometer (Hand-Grip Strength, HGS) and a Bio-Impedance-Analysis Phase angle (BIA/PA).

The **SENS trial** aims at exploring the feasibility, acceptability and appropriateness of an advance care planning (ACP) intervention in the daily practice of a medical oncologist in a pilot trial.

A pilot trial **evaluating decisional conflict and regret in clinical cancer trials.** It aims at systematically investigating the decision-making process of patients who have been invited to participate in a clinical cancer trial.

A qualitative trial that aimed at describing **patient-reported experiences of cancer care during the COVID-19 pandemic in Switzerland** was approved by the board in August 2020. All trial-related activities were stopped in November 2020 due to the financial restructuring of SAKK. After a transfer of sponsorship in 2021 to the principal investigator's (Prof. Dr. rer. med. Manuela Eicher) affiliation, the trial was conducted at five sites in the German, French, and Italian speaking parts of Switzerland. In total, 65 interviews with cancer patients were conducted between March and August 2021: 35 in French, 18 in German, and 9 in Italian. The analyses were still ongoing as of the end of 2021, with the final results expected in Q1 2022.

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, was published in *BMC Cancer* in February 2021.

At the Semi-Annual Meeting in November 2021, Prof. Dr. med. David Blum was elected as the new president of the group. Members interested in acting as vice president(s) are encouraged to apply.

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 2021, the membership of the Section Network for Cancer Predisposition Testing and Counseling (CPTC) increased significantly: undoubtedly thanks to growing interest in the domain of oncogenetics and its increasing role in therapeutic decision-making. In 2021 the training course was held twice for the first time: in St.Gallen in June and, for the first time, in Lausanne in September in order to cater to the French-speaking collaborators.

New testing and counseling criteria for hereditary breast and ovarian cancer were published in the *Swiss Medical Weekly* in September. This publication was spearheaded by Dr. med. Susanna Stoll and CPTC vice president Dr. med. Salome Riniker.

After the successful revision of HIBO Art. 12d letter d regarding breast monitoring (mammography and MRI) for women with increased risk of breast cancer, the FOPH asked the CPTC, specifically PD Dr. med. Cornelia Leo and the president of the CPTC, PD Dr. med. Sheila Unger, to revise Art. 12b (preventive surgeries). A committee was then formed consisting of representatives from the CPTC and the Swiss societies of senology, genetics, and

gynecology, and the Swiss Cancer League. A draft version should be available before the SAKK Semi-Annual Meeting in May 2022.

Our annual educational session was once again a success. To celebrate the return of in-person meetings, Dr. med. Bettina Bisig from Lausanne University Hospital (CHUV) was invited to give a talk on the role of the pathologist in hereditary cancer syndromes, which was extremely well received.

The CPTC network will continue to work on various projects in 2022, including the election of a new president in November.

Section Pathology

President: Prof. Dr. med. Chantal Pauli, University Hospital Zurich

The Section Pathology represents a diagnostic and scientific platform that aims to offer support particularly for translational research issues and in association with clinical trials.

It is also involved in the quality assurance of clinical trials regarding pathology diagnoses and compliance with pre-analytical and analytical standards in tissue-based analysis. It sets standards for the application of methods such as immunohistochemistry, in-situ technologies (e.g. fluorescence in-situ hybridization) and the now commonly used molecular pathology analysis. Molecular pathology services can be offered to clinical trials or translational projects e.g. **SAKK 16/14** (Anti-PD-L1 antibody durvalumab in addition to neoadjuvant chemotherapy in patients with stage IIIA [N2] NSCLC).

Furthermore, pathology supports the development of new analytical methods, their establishment and operations. An overarching goal is the quality and maintenance of archival tissue, tissue biobanking and living cell biobanks. At the same time, it initiates and runs its own projects in close collaboration with the organ-specific SAKK project and working groups.

Of note is the project currently led by Prof. Dr. med. Rupert Langer, director of Pathology and Molecular Pathology at Johannes Kepler University in Linz and Kepler University Hospital (formerly at the University of Bern). Prof. Dr. med. Rupert Langer implemented the translational research project associated with the trial **SAKK 75/08** (cetuximab in neoadjuvant therapy of esophageal cancer), in which molecular signatures are being characterized using comprehensive molecular genomic and methylation methods in patients' tumor tissue that are 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)

Trials to optimize immunomodulation and perioperative concepts

Modern radiation techniques allow an application of high doses per fraction with perfect precision, and thus represent a highly tolerable treatment for very sensitive structures such as the lung as well as for vulnerable areas immediately after resection, such as in the axilla.

Therefore, the Section RadioOncology continued with patient accrual after the reopening of the **TAXIS trial** of individualized oncological treatment of node-positive breast cancer (formerly SAKK 23/16). It was made feasible by a rapid transfer of data and know-how from SAKK to University Hospital Basel. The trial will answer the question of whether restrictive axillary surgery can be compensated by precisely planned dynamic intensity modulated radiation therapy (IMRT/VMAT) of the regional lymph nodes. The high accrual in late 2021 was able to fill the gap caused by the new ethical application and the data transfer from SAKK to Basel in summer 2021. As of the end of 2021, more than 430 patients had been randomized in the trial. The quality assurance process of TAXIS continues, and it is the largest effort on treatment quality ever made in the Swiss radiation oncology community within a clinical trial. The first data on the feasibility of the trial were also published successfully in 2021.

In locally advanced, but resectable stage III (N2) non-small cell lung cancer (NSCLC) (**SAKK 16/18**), immune-modulatory stereotactic and image-guided radiotherapy focused on the primary was able to be continued as a multicenter single-arm phase II trial. More than 25 % of the required patients have been accrued, but the inclusion is falling short of expectations, in part due to the suspension of accrual at the beginning of the year. The members of the section have been reminded to motivate patients to participate, especially the sites that have not yet been able to recruit patients.

Unfortunately, two important prostate cancer trials had to be closed prematurely, and the responsibilities for a minimal follow-up have been transferred to Inselspital Bern (University Hospital of Bern) (SAKK 08/15 PROMET on tumor recurrence) and Cantonal Hospital St.Gallen (SAKK 63/12 Biobank). Many sites of the Section Radio-Oncology have agreed to support this effort.

The section members are currently discussing new concepts in order to continue with trials evaluating the value of hypofractionated, image-guided and stereotactic treatments in solid and limited metastasized malignancies, such as in pancreatic cancer, to improve local symptom control and/or to delay tumor progression in order to enable optimal efficacy of systemic antibody therapies or immunotherapies.

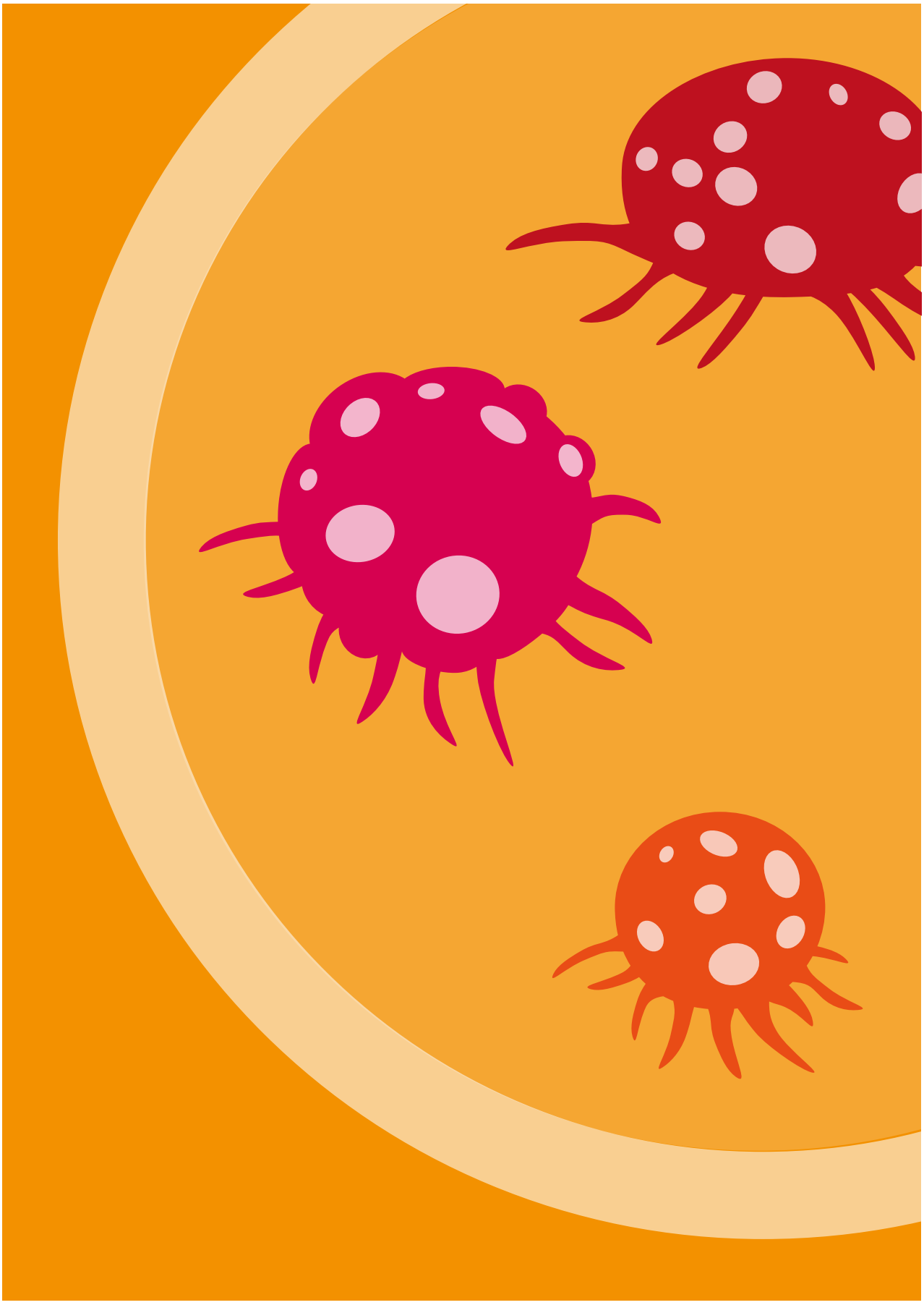
Section Registries

President: PD Dr. med. Ulf Petrausch,
OnkoZentrum Zürich
Vice president: Dr. med. Petros Tsantoulis,
Geneva University Hospitals (HUG)

The section was founded in 2021 and wants to establish itself as the platform for the analysis of medical data collected in the SAKK network. The section welcomes representatives from different indications and disciplines (oncologists, pathologists, radiologists, data scientists) to create an innovative environment for this rather new approach to improving patient care.

Within the last few years, the SAKK platform Swiss Centralized Oncology Real world Evidence Data (SCORED) has been established to allow data collection from patients in the SAKK network. The section's central task is to maintain and guarantee the collection of medical data, thus enabling the optimal interchangeability of medical data between projects inside and outside SAKK. This is a scientifically interesting and structurally challenging field. The challenges cover a wide variety of different subjects, such as rights of the patient, ethical issues, legal contracts, informed consents, innovative analysis methods, and the definition of relevant clinical subgroups. Moreover, the interaction with other Swiss initiatives such as the Swiss Personalized Health Network (SPHN) and Swiss Personalized Oncology (SPO) is of pivotal interest to the section. In recent months, a common nationwide core data set has been defined in order to embed the SCORED data into a wide field of data analysis science.

The first, already complete data registry is the **AlpineTIR registry (SAKK 80/19)** which collected data from 705 patients treated with checkpoint blockade therapy in different entities. The **CaSA (SAKK 80/20)** is another early prime example of a registry in the context of SCORED. The publication of the outcome data of SARS-CoV-2 infection in cancer patients attracted international attention at the ESMO 2021 meeting. With great enthusiasm, the section helps to analyze subgroups of the AlpineTIR register such as patients taking bone-targeting agents and melanoma patients. the section also supports the creation of new registries; projects relating to molecular testing, kidney cancer and lung cancer are currently in preparation.



Interview with PD Dr. Dr. Martin Reist, SAKK CEO

The business year 2021 was extremely challenging for SAKK. How would you summarize it?

I think it turned out largely positive overall. We were able to secure the future of SAKK. Financially speaking, SAKK is on a solid footing. We learned from the past and accordingly adapted our structures and modernized our governance. We were able to open nine new trials, and a large number of trials that had been temporarily suspended were reopened or transferred to other sponsors. This outcome was tarnished by the dismissal of employees through no fault of their own, by interventions in trials that badly affected the researchers, and by the loss of confidence that SAKK suffered as a result of its crisis.

If we compared your schedules from January 2021 and 2022, what would be the most striking differences?

The main focus in 2021 was on safeguarding the existence of SAKK and then on reorganizing and modernizing its structures and governance. We succeeded on both counts. In 2022 the core issues are the need to implement the reforms, open new trials, and boost confidence.

The future of SAKK has been materially assured by the restructuring that has taken place. Who are the main sponsors that will sustainably safeguard its existence?

SAKK is a clinical research organization of national importance. The comprehensive networking of university, cantonal, regional, and private hospitals with the aim of promoting and performing national and international clinical trials is of inestimable value for cancer patients, research, the health care system and for industry. Our long-standing partners and our members have realized this. In this context, the confidence and support offered by the State Secretariat for Education, Research and Innovation (SERI) is also of major significance.

SAKK will soon turn 60. It was restructured effective January 1, 2022. The network of committees is now denser. What do you feel are the major advantages of the new organizational structure at SAKK?

The members now have an additional voice in the form of the Strategic Council. The SAKK Board has not only become smaller and more agile but, now that it is open to "non-oncological" Board members representing the health care system, health economics, public health policy and business, it also has a broader base with a wider range of skills. The creation of the independent Scientific Committee separated project evaluation from Board functions.

The creation of the Board of Directors, which meets on a monthly basis and includes the President, the Chair of the Scientific Committee and the CEO, will speed up decision-making processes.

What are the most important lessons that you and the Management Board of the Coordinating Center have learned from the restructuring?
Confidence between the members of the Management Board has grown during this period. We have realized that we achieved more than we thought. Open and transparent communication was extremely important: the full extent of the crisis had to be disclosed rather than coming out with the sad truth bit by bit. It was also important to communicate that there is a plan for exiting the crisis – and to explain what the specific next steps would be at each stage. To radiate calm and confidence, both within the organization and to the outside world. And stubbornness and assertiveness were also needed to stick with the restructuring plan. It was important to repeatedly consult with the Board and for everyone to pull together. I think we'd do things very much the same way if we had to work through a crisis again.

Crisis prevention efforts already set the correct course before the crisis became apparent. However, the structural deficit was already too large at this point for crisis prevention to have had an effect. In the future, though, the tools and processes we created will allow us to detect any imbalances immediately, at an early stage.

Decisions had to be taken and implemented last year that were no doubt unpopular. Yet SAKK was able to fulfill its performance mandate at all times. What was the crucial aspect that enabled you to come through this demanding phase so successfully?
It was a combination of various elements. The most important was probably genuine humility. Putting your own feelings aside and concentrating on the big picture – and on the people who were feeling powerless. Not returning or transferring frustration and anger unchecked but rather accepting it – without letting it eat away at you. Being able to apologize for situations that you hadn't caused. To do all that, you need to be well grounded and have strong values. I was extremely fortunate to have had very good role models in my family and at previous stages of my career. They helped me without even realizing it. The support given by colleagues at the Coordinating Center and the ability to talk things over with them were also very important. Most of all I am grateful to my dear, strong wife and my children. I can't imagine it was always a pleasure to live with me during the past 18 months.

Dr. Christine Aeschlimann, Program Manager Patient Advisory Board

SAKK Patient Advisory Board

SAKK's actions focus on patients and their families. Our aim is to partner with patient groups and patient advocates to achieve decisive and sustainable improvements in cancer therapy. The Patient Advisory Board was set up in 2015 and incorporated into the SAKK bylaws in 2017. The members of the Patient Advisory Board are directly or indirectly affected by cancer, have experience of trials and/or represent patient groups, and/or have a professional background in clinical research. The Patient Advisory Board currently has seven members who, with great personal dedication and motivation, provide valuable support for SAKK's activities.

The Patient Advisory Board met six times in the year under review, it organized two free public events for experts and patients alike (see below), and completed a joint course of continuing education. The Board was also involved in various SAKK trials (e.g. in the review of patient information for the trials), and was actively requested to participate in external researchers' projects.

Communication-related input from the Patient Advisory Board members is in particularly high demand. The Board's priority in 2021 was accordingly the development of summaries of completed trials in language accessible to non-experts. The **communication of trial findings to trial subjects and to the public** is an urgent necessity for a non-profit organization like SAKK. This activity has been mandatory in the EU since February 2022, and in the future SAKK will voluntarily create this transparency in all its trials, thus playing a pioneering role throughout Switzerland. In 2021 the first-ever non-expert summary was created for SAKK trial 25/14, which is investigating a new first-line therapy for metastatic breast cancer, and translated into three official languages. All the members of the Patient Advisory Board completed continuing education in good lay summary practice in preparation for this task, and a joint workshop was held with the medical writer at SAKK.

In addition to this highly topical subject, the Patient Advisory Board organized a **discussion group** on **"Lay summaries of clinical trial results"** on November 20, 2021 to tie in with the Swiss Oncology and Hematology Congress (SOHC). Experts from the pharmaceutical industry and the umbrella organization of the Ethics Committees contributed to the discussions, and a cancer patient gave a very moving account of her perspective. The well-attended event was skillfully moderated by Dr. Ursula Ganz-Blättler, a member of the Patient Advisory Board, and clearly illustrated the significance of the issue. Lay summaries of further SAKK trials will be deployed and published in the coming years, and the process will be integrated into the SAKK standard procedures.

Another event organized by the Patient Advisory Board focused on the highly topical issue of **COVID-19 and cancer.** The Patient Forum on May 6, 2021 was held virtually because of the pandemic. Three lectures by experts illustrated the situation of cancer patients from three different professional perspectives and talked about vaccination. The interesting and well-attended event was moderated by Dr. Sander Botter, who has been a member of the Patient Advisory Board for several years and is himself a researcher.

The Patient Advisory Board developed a **position paper** on the popular initiative to ban research involving animals and humans, in which it recommended that the initiative should be rejected. It also commented on accompanying research performed to implement the cancer registry in Switzerland.

The valuable support provided by the Rising Tide Foundation for Clinical Cancer Research will make it possible for the Patient Advisory Board to continue elaborating the trial summary project and organizing events in the coming year. We are very grateful for this support.

Interviews with Clinical Research Coordinators (CRC)

Ruth Demmer-Steingruber,
Cantonal Hospital St.Gallen

"New approaches to therapy are emerging all the time, so my work is always interesting"

Ruth Demmer-Steingruber is Head of Trial Coordination in the Department of Clinical Research Oncology/ Hematology at Cantonal Hospital St.Gallen. A trained nurse with an additional qualification in intensive care, she has been a Clinical Research Coordinator (CRC) in St.Gallen for 20 years. In an interview, she explains how her job has changed during this time.

Ms. Demmer, how did you come to be a CRC?

I spent two years in the USA as a young woman. When I returned, I looked for a job that would let me combine my English skills with my nursing skills – and that led me to the job as CRC. I celebrated 20 years in this function in February 2022. The job has changed greatly during this time. I'm not doing the same work as before.

What are the most striking changes?

The switch from paper to electronic format was a turning point; the team had to get used to entirely new processes. And the administrative side of the work has increased enormously; today even the smallest steps have to be documented clearly. The information provided to patients is much more extensive too. When I started this job, the information was five pages long; nowadays there are between 20 and 30 pages. It's a big challenge for patients to understand it all. Patients are informed primarily by the doctors, but I answer trial subjects' questions about practical aspects, for example, how long patients have to stay on the site after they have taken their tablets, how many blood samples are taken, and so on.

What are your most important tasks as CRC?

I look after the patients in trials, and I also handle organization, logistics, and documentation. In the morning, for example, I prepare medication, give a patient an infusion and monitor them. Once the patient has gone home, the desk work starts. I document data about the patient and the examinations performed in the electronic Case Report From, contact the sponsor, request assessments from doctors, etc. There are always around 50 active trials ongoing here in St.Gallen. I am responsible for some of them and have nothing to do with others.

What are your favorite aspects of your work – and what are your least favorite?

Research is changing and new approaches to therapy are emerging all the time, so my work is always interesting. I also really enjoy the direct contact with patients. Another positive aspect is the interdisciplinary nature of the work, the opportunity to interact with people from many different professions – doctors, nurses on the wards, people employed by the sponsor, etc., although this close collaboration does mean that we are each dependent on other people. As CRCs we must ensure that things are done at the right time and that information is passed on promptly. We sometimes need to remind those responsible that these tasks have to be done punctually. That's not always easy.

What role does SAKK play in your work?

When a trial is being set up, a phase in which a lot of documents have to be completed, I work very closely with the Clinical Research Associates (CRA) and Clinical Project Managers (CPM) at SAKK. During the trial, too, we are often in contact with each other to exchange information – the CRAs and CPMs need to clarify things, and we CRCs have questions as well. The six-monthly CRC meetings are also important for us CRCs. They are always attended by one or two members of the team. Something else that we greatly appreciate are the continuing education days organized by SAKK for new CRCs. These days are enormously valuable in introducing people to this very specific type of work.

Dr. Luisa Granziero,
Oncology Institute of Southern Switzerland (IOSI)

"Scientific information only becomes knowledge if many people work together"

Dr. Luisa Granziero has been a Clinical Research Coordinator (CRC) at the Oncology Institute of Southern Switzerland (Istituto Oncologico della Svizzera Italiana, IOSI) since 2019. With a doctorate in bioscience and biology, she worked in research for 13 years before moving into scientific communication. The most important aspect of her work is the interaction with people from many different professions.

Dr. Granziero, what are your most important tasks as CRC at the IOSI?

The CRCs coordinate clinical research. We need to know exactly what the trial protocols require. We work with the other team members – investigators, study nurses, pharmacists and sponsors – to ensure that all the activities described in the protocol are performed correctly and on time and that they are documented.

What are your favorite aspects of your work – and what are your least favorite?

I really enjoy working with the team members from other professions. Together we can offer people with cancer treatment options that they would otherwise not have had. It's always difficult for me when I have to record a death, even though that's simply part of oncology trials. When that happens, I try to remember that bad outcomes are also important in helping us learn more about a treatment.

What's the biggest challenge in your job?

Keeping the bigger picture in mind and never losing sight of the objective – and that's the patient. It's not always easy because my day-to-day work consists of many activities for which the rationale is not immediately clear. For instance: reporting a minimal change in the dose of a "trivial" concomitant medication, documenting that vital parameters were measured with the patient sitting, performing an examination within an exact time slot, etc. This precision is not meaningless, though; it's the basis of science. The data must be reproducible and comparable. Only reliable data can be evaluated and are useful for the sponsor, the specialists in the hospital, the scientific community and, above all, patients.

How do you collaborate with SAKK?

As a coordinating institution, SAKK is of fundamental importance and provides indispensable support for us CRCs. We turn to SAKK with our doubts, problems, need for clarification and questions – and receive professional responses from cooperative, attentive, friendly individuals. The people working at SAKK and we, the CRCs, have the same aim: to use the trial as a tool for achieving the best-possible level of well-being for a patient at this point in their medical history.

Can you identify a highlight of your work?

I always find our update meetings particularly interesting. The team working on a clinical trial meets once a week, and we use these meetings to share the latest information about all active, screened, and potential patients. I always realize something very important at these meetings: there's not much that one person can do in a completely autonomous context. Scientific information only becomes knowledge when a working group consisting of many specialists performs the trial and writes an article about it. Reviewers assess the article, people working for the scientific publishing house handle the publication, and often the results are subsequently presented at a congress. The work done by a small group can only become general knowledge through many people working together.

Christine Biaggi Rudolf,
Chief Operations Officer (COO)

Céline Hummel,
Chief Quality & Compliance Officer

Trial Activities and Quality Assurance

Trial and Patient Figures

Trial activities were very limited in 2021 in comparison with previous years. The financial restructuring forced us to stop patient recruitment into some trials, while recruitment for others had to be closed prematurely. It was possible to transfer a few trials to a new sponsor, ensuring that patients could be recruited outside of SAKK.

As a result of this situation, we were not nearly able to match the figures for the previous year. We recruited a total of 540 patients into the 33 remaining open trials conducted by SAKK (including retrospective studies and registries), 357 of them in prospective trials. 506 of the 540 patients were recruited via the SAKK member hospitals.

The exceptionally good news is that, in spite of the difficult circumstances, we were able to open nine new trials in 2021. Four of these are SAKK trials and five are trials performed in conjunction with European collaborative groups.

Cooperation with Swissethics, the Ethics Committees, and Swissmedic

The number of trials submitted to and approved by the authorities in 2021 was slightly lower than the previous year because of the restructuring of SAKK. Despite this difficult situation, cooperation with the Ethics Committees, Swissethics and Swissmedic was once again very good in 2021. Reporting to Swissethics on the scientific and ethical criteria of SAKK trials in the context of the financial restructuring was successfully completed.

The Quality Assurance team successfully performed audits

In spite of the ongoing pandemic-related difficulties, the QA team performed three phase I requalification audits and a GCP site audit in the year under review. All but one were performed on site. The audit performed virtually because of the tense situation at the end of the year enabled the QA team to gain valuable experience, and in the future it will be possible to perform more audits remotely, guided by risk assessment.

This year, moreover, SAKK's QA system was audited by a German sponsor for whom we are conducting a trial in Switzerland. The outcome of this audit was extremely positive! No findings were identified, and at the end of the process the sponsor confirmed that SAKK is in a very good position in all the areas audited, and is performing outstanding work.

The M-Files document management system that has been used successfully since 2019 to file, process, and manage trial documents in the form of an electronic Trial Master File (eTMF) was expanded this year to include the management of SOPs (Standard Operating Procedures). SOPs can now be processed and managed directly in M-Files. Changes are unambiguous and clear (audit trail). In addition, the version control in M-Files ensures that everyone accesses the current version of SOPs and their annexes. At the same time, the SOP training process was implemented directly in M-Files, making it much easier for individual employees and the QA team to navigate the training process, including signatures, and maintain an overview. A good half of all the SAKK SOPs had been transferred to M-Files by the end of 2021.

Dr. Stefanie Hayoz,
Head of Statistics

A further milestone in the digitalization of SAKK

This year the first trials were opened in which serious adverse events (SAEs) were recorded electronically. In contrast to previous practice, the trial sites no longer report SAEs to the Safety Office on paper via fax, but by entering them directly into secuTrial®, the electronic data capture system. The physicians sign these reports electronically rather than on paper. Initial experience during this pilot phase is largely positive. Input from the sites is recorded and implemented on an ongoing basis to enable the system to be established on a broad base in the future, thus making the SAE reporting process much more efficient for everyone involved.

Trial Results and Publications

Last year, 35 articles involving SAKK appeared in various scientific journals. The full list can be found on page 57–62.

SAKK was well represented at the major oncology congresses as well as more local events with 14 posters and 21 oral presentations.

Notably, there were four posters and four oral presentations at the European Society for Medical Oncology (ESMO) congress with SAKK involvement, including two oral presentations of SAKK trials. A full list of all posters and presentations can be found on page 63–65.

As part of our statistical advisory work, we were also able to assist with about 17 smaller and larger non-SAKK projects and contribute to presentations and manuscripts.

The statistics team produced 18 clinical trial reports, including nine final reports for the authorities.

	2020	2021	Change	Percent
Total patients	**1896**	**540**	**–1356**	**28 %**
Patients in Switzerland	1699	506	–1193	30 %
Patients in foreign countries	197	34	–163	17 %
Patients in SAKK trials	1612	394	–1218	24 %
Patients in trials with other cooperative groups/partners	284	146	–138	51 %
Patients in clinical trials	1186	357	–829	30 %
Patients in retrospective trials, cohort trials, biobanks and registries	710	183	–527	26 %
Studies open for patient recruitment	**58**	**33**	**–25**	**57 %**
SAKK trials	33	14	–19	42 %
Trials with other cooperative groups/partners	25	19	–6	76 %

Balance sheet

As of December 31 (in CHF)	**2021**		**2020**	
Assets				
Cash and cash equivalents	9’752’064		4’550’582	
Accounts receivable	2’700’005		3’339’791	
Other accounts receivable	395’076		63’486	
Prepaid expenses and deferred income	722’403		1’649’395	
Total current assets	**13’569’548**	42.5 %	**9’603’254**	36.3 %
Financial assets	18’364’948		16’833’328	
Total fixed assets	**18’364’948**	57.5 %	**16’833’328**	63.7 %
Total assets	**31’934’496**	100.0 %	**26’436’582**	100.0 %
Liabilities				
Accounts payable	2’152’355		3’450’751	
Other accounts payable	228’929		425’213	
Deferred income and accrued expenses	15’698’855		8’912’653	
Total short-term liabilities	**18’080’139**	56.6 %	**12’788’617**	48.4 %
Provisions for liability claims				
Other Provisions	–		–	
Total long-term liabilities	**–**	–0.0 %	**–**	–0.0 %
«Education Grant» fund	–		60’000	
«Special purpose» fund	217’932		217’932	
«Hubacher» fund	10’216’653		9’744’483	
Total special purpose fund capital	**10’434’586**	32.7 %	**10’022’415**	37.9 %
Organizational capital				
Free capital as at 1 January	3’625’550		4’021’669	
Group result	–205’779		–396’118	
Free capital as at 31 December	3’419’771		3’625’550	
Total organizational capital	**3’419’771**	10.7 %	**3 ’625’550**	13.7 %
Total liabilities	**31’934’496**	100.0 %	**26’436’582**	100.0 %

Statement of operations

January 1 to December 31 (in CHF)	**2021**		**2020**	
Operating income				
Research contributions SERI[1]	5'891'000		6'094'734	
Research contributions CLS[2]	159'450		281'450	
Research contributions CRS[3]	1'036'509		1'781'250	
Research contributions SSKK[4]	100'000		100'000	
Research contributions, third parties	280'483		900'203	
Research contributions, Swiss health insurers	1'497'631		1'632'615	
Income from industry partnerships	3'435'940		3'620'933	
Income from foreign study groups	181'511		606'878	
Income from Cancer Bulletin	173'377		219'089	
Income from Patient Advisory Board	50'028		70'028	
Donations, bequests, legacies	548'798		1'948'483	
Miscellaneous income	1'573'001		1'218'793	
Losses on receivables	158'307		–21'999	
Total operating income	**15'086'034**	100.0 %	**18'452'456**	100.0 %
Operating costs				
Miscellaneous study-related expenses	–2'010'084		–2'059'058	
Research contributions IBCSG, ETOP[5]	–100'322		–295'942	
Research contributions, centers	–1'790'437		–5'669'183	
Travel, hospitality expenses	– 1'204'637		–1'191'975	
Other operating expenses	–78'009		–124'718	
Total operating expenses	**–5'183'489**	–34.4 %	**–9'340'877**	–50.6 %
Interim result 1	**9'902'545**	65.6 %	**9'111'579**	49.4 %
Coordination expenses				
Personnel expenses	–8'110'929		–9'575'356	
Other coordination expenses	–1'124'305		–1'681'524	
Total coordination expenses	**–9'235'234**	–61.2 %	**–11'256'880**	–61.0 %
Interim result 2	**667'312**	4.4 %	**–2'145'301**	–11.6 %
Financial result				
Financial income	904'342		221'160	
Financial expenses	–315'110		–187'359	
Total financial result	**589'231**	3.9 %	**33'801**	0.2 %
Interim result 3	**1'256'543**	8.3 %	**–2'111'500**	–11.4 %
Out-of-period result				
Out-of period income	–		1'880'379	
Out-of period expenses	–1'462'322		–164'997	
Total out-of-period result	**–1'462'322**	–9.7 %	**1'715'382**	9.3 %
Annual result	**–205'779**	–1.4 %	**–396'118**	–2.1 %

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 2021 annual financial statements

As of December 31	2021	2020
Information compliant with Art. 957–962 SCO		
Number of personnel		
Bandwidth of full-time equivalents (average for year)	>50 bis 250	>50 bis 250
Valuation of assets at market value		
Financial investments at market value on 31.12	18'364'948 CHF	16'833'328 CHF
Of which securities Hubacher fund	10'252'678 CHF	11'659'071 CHF
Net accounts receivable	2'700'005 CHF	3'339'791 CHF
Accrued liabilities and deferred income		
Future payments SAKK	1'046'866 CHF	1'428'358 CHF
Solidarity	1'185'528 CHF	–
Study accruals and deferrals	4'808'803 CHF	124'175 CHF
Ongoing study accruals and deferrals	5'459'095 CHF	4'664'726 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	56'321 CHF	69'073 CHF
Fixed rental contract (offices) up to 30.4.2026	1'174'099 CHF	1'445'045 CHF
Fixed rental contract (offices) up to 30.8.2027	491'073 CHF	577'734 CHF
Total	1'721'494 CHF	2'091'852 CHF
Notes on extraordinary, non-recurring or out-of-period items in the income statement		
Out-of-period expenses	–1'462'322 CHF	–164'997 CHF
Out-of-period income	0 CHF	1'880'379 CHF
Total	–1'462'322 CHF	1'715'382 CHF
Cost reductions as a result of the restructuring are included here.		
Net release of hidden reserves	0 CHF	273'853 CHF

SAKK is an association based in Bern. 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 2021 annual financial statements, research projects were again 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. In addition, all inflows from 2021 that serve to cover costs in 2022 and subsequent periods were for the first time deferred on a project-specific basis.

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 funds not exceeding the federal financial contributions for 2022–2024 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. Asymmetrically incurred costs were taken sufficiently into account here. Income surpluses in 2021 that serve to cover costs in 2022 and subsequent periods were apportioned to the years and deferred.

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

RÖTHLISBERGER

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cpaai

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, 2021.

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 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

RÖTHLISBERGER

the reasonableness of accounting estimates made, as well as evaluating the overall presentation of the financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements for the year ended December 31, 2021 comply with Swiss law and the bylaws.

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.

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

Berne, April 27, 2022 fc/ro
1434

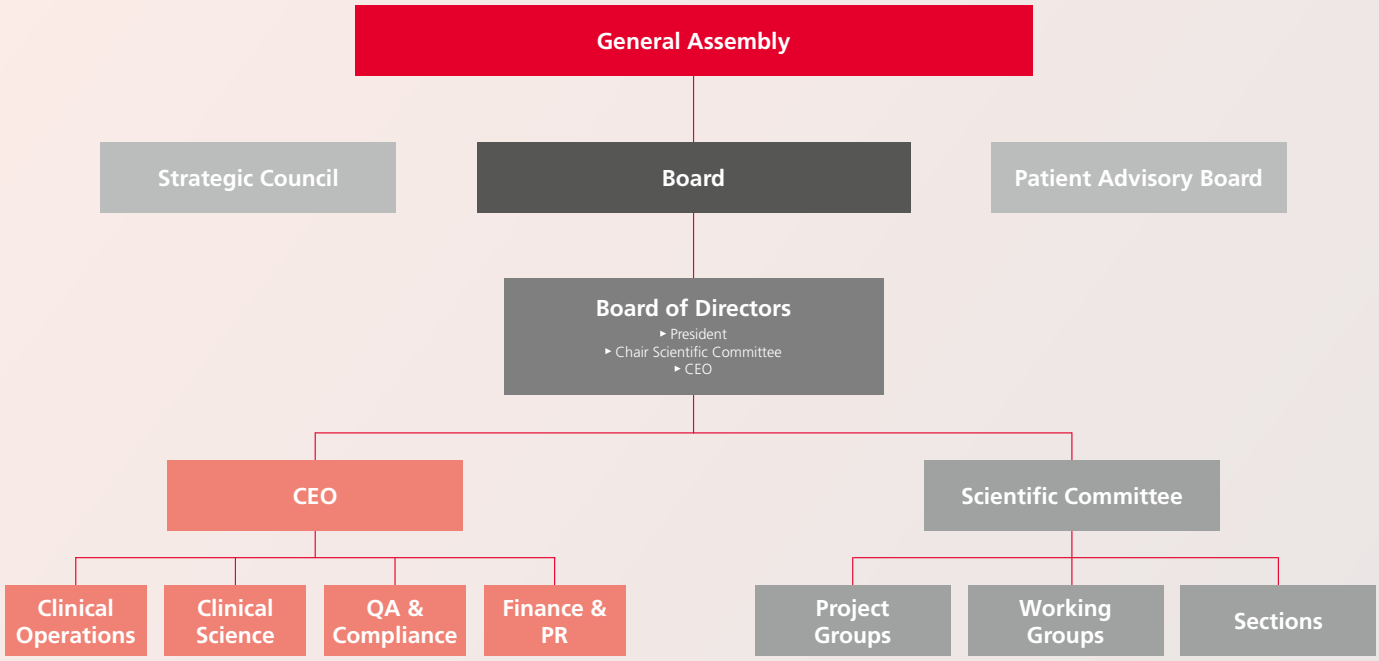
Dr. Röthlisberger AG

Fabrizio Conoscenti
Swiss Certified Public Accountant
Audit Expert
(Auditor in Charge)

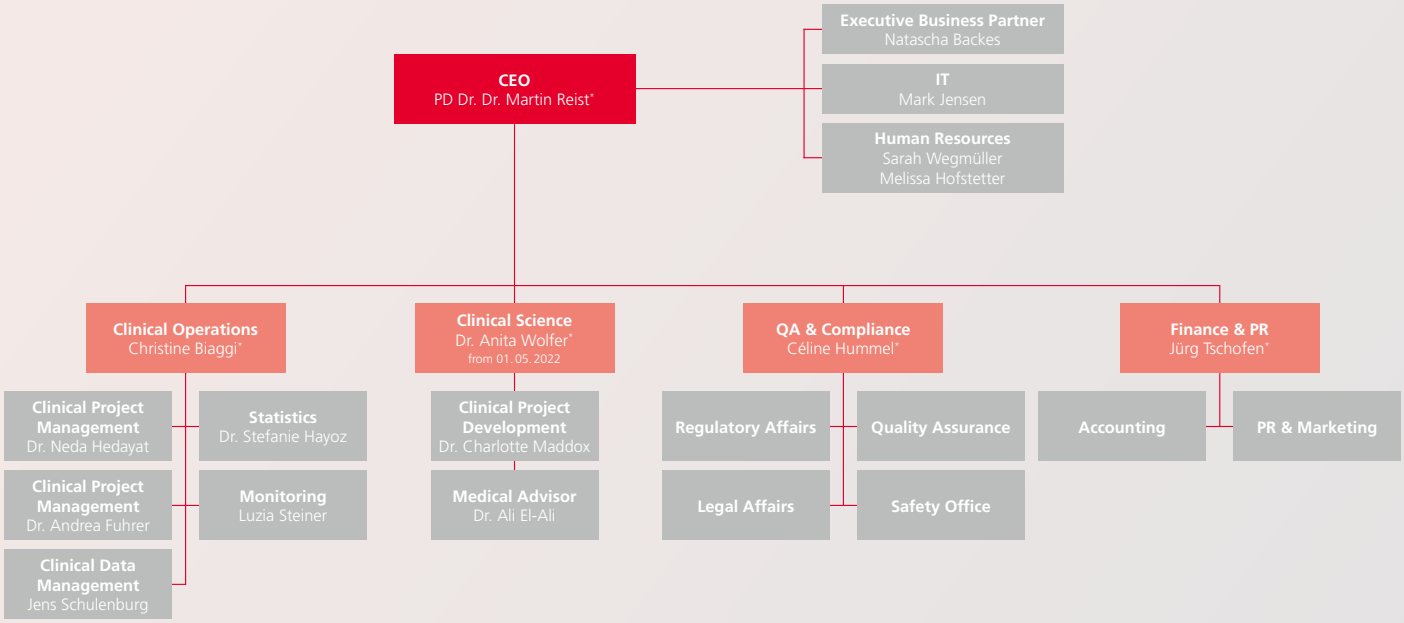
Romano Jungo
Swiss Certified Public Accountant
Audit Expert

- Financial statements (balance sheet, income statement, cash flow statement, the statement of changes in equity, the statement of changes in funds and notes)
  Balance sheet CHF 31'934'496 / Annual loss CHF -205'779

SAKK Organization Chart



SAKK Coordinating Center



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President

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Prof. Dr. med.
Urban Novak

Dr. oec. HSG
Willy Oggier

PD Dr. med. Dr. phil. nat.
Sacha Rothschild

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Martin Früh
Chair of the SAKK Scientific Committee

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Brigitta Baumert

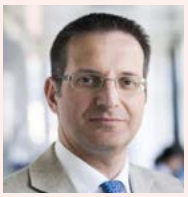
Dr. med.
Thibaud Kössler

Prof. Dr. med.
Anja Lorch

Prof. Dr. med.
Christoph Mamot

Dr. med.
Berna Özdemir

Prof. Dr. med.
Chantal Pauli



Prof. Dr. med.
Davide Rossi

Prof. Dr. med. Dr. phil.
Andreas Wicki

Dr. med.
Thomas Zilli

Board of Directors

Prof. Dr. med.
Miklos Pless

PD Dr. Dr.
Martin Reist

Prof. Dr. med.
Martin Früh

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
– Claudia von Schilling Foundation for Breast Cancer Research
– CSS Krankenversicherungs AG
– Elisabeth Hilti Stiftung e
– Fondation pour la Recherche et le Traitement Medical
– Fondazione Istituto di Ricerche Farmacologich
– Foundation St.Gallen Oncology Conferences (SONK)
– Gateway for Cancer Research
– Graubünden Cantonal Hospital Foundation
– Hedy Glor-Meyer Stiftung
– Helsana supplementary insurance
– Hilty Family Foundation
– Promedica
– Rising Tide Foundation for Clinical Cancer Research
– santésuisse
– Schweizerische Stiftung für Klinische Krebsforschung (SSKK)
– Stiftung IQmed
– Stiftung zur Krebsbekämpfung

Academic research
– Roche Pharma Schweiz AG

SAKK Industry Pool 2021
Sincere thanks to the following pharmaceutical companies for their support:
– AbbVie AG
– Amgen Switzerland AG
– Astellas Pharma AG
– AstraZeneca AG
– Bayer (Schweiz) AG
– Boehringer Ingelheim (Schweiz) GmbH
– Bristol-Myers Squibb SA/ Celgene GmbH
– Daiichi Sankyo (Schweiz) AG/ AstraZeneca AG
– Eli Lilly (Suisse) SA
– Exact Sciences International Sàrl
– Gilead Sciences Switzerland Sàrl
– GlaxoSmithKline AG
– IDEOGEN AG
– Incyte Biosciences International Sárl
– IPSEN PHARMA GmbH
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– Janssen-Cilag AG
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– Pierre Fabre Pharma AG
– Roche Pharma (Schweiz) AG
– Sanofi-Aventis (Schweiz) AG
– Servier (Suisse) S.A.
– Takeda Pharma AG
– Vifor AG

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PostFinance AG, Mingerstrasse 20, 3030 Bern
BIC/SWIFT: POFICHBEXXX
Clearing no. (BLZ): 9000

Conducted Trials 2021

Trials activated in 2021

Trial name	Trial title	Coordinating investigator	Activation
Developmental Therapeutics			
BASILEA CDI-CS-002	An open-label Phase 1/2a study of oral BAL101553in adult patients with advanced solid tumors and in adult patients with recurrent or progressive glioblastoma or high-grade glioma.	Thomas Hundsberger	15.02.2021
BAY 1895344	A multicenter, non-randomized, open-label phase 1b study to determine the maximum tolerated and recommended phase 2 dose of the ATR Inhibitor BAY 1895344 in combination with pembrolizumab and to characterize its safety, tolerability, pharmacokinetics and preliminary anti-tumor activity in patients with advanced solid tumors.	Markus Jörger	14.04.2021
SAKK 67/20	Open-label dose escalation phase 1b trial of a new micellar docetaxel compound in patients with metastatic castration-resistant prostate cancer.	Ilaria Colombo	28.05.2021
Gynecological Cancer			
AGO-OVAR	Atezolizumab in combination with Bevacizumab +/- Chemotherapy versus Chemo-Bevacizumab standard in recurrent ovarian cancer – a randomised Phase III trial.	Christian Kurzeder	04.03.2021
Leukemia			
CLL 17	A phase 3 multicenter, randomized, prospective, open-label trial of ibrutinib mono-therapy versus fixed-duration venetoclax plus obinutuzumab versus fixed-duration ibrutinib plus venetoclax in patients with previously untreated chronic lymphocytic leukemia (CLL).	Michael Gregor	16.12.2021
HOVON 155	A randomized phase II multicenter study to assess the tolerability and efficacy of the addition of midostaurin to 10-day decitabine in UNFIT (i.e. HCT-CI >= 3) adult AML and high risk myelodysplasia (MDS) (IPSS-R > 4.5) patients. A study in the frame of the masterprotocol of parallel randomized phase II studies in UNFIT- AML/high-risk MDS patients.	Sabine Blum	08.07.2021
Lung Cancer			
SAKK 15/19	Thoracic radiotherapy plus maintenance Durvalumab after first line Carboplatin and Etoposide plus Durvalumab in extensive-stage disease small cell Lungenkrebs cancer (ED-SCLC) A multicenter single arm open label phase II trial.	Alfredo Addeo	24.06.2021
SAKK 17/18	Overcoming Resistance to Immunotherapy combining Gemcitabine with atezolizumab in advanced NSCLC and mesothelioma progressing under immune-checkpoint inhibitors or gemcitabine. A multicenter, single-arm, open label phase II trial with two cohorts.	Alessandra Curioni-Fontecedro	02.03.2021
Lymphoma			
SAKK 38/19	Assessing a ctDNA and PET-oriented therapy in patients with DLBCL. A multicenter, open-label, phase II trial.	Anastasios Stathis	08.06.2021

Trials open for accrual in 2021

Trial name	Trial title	Coordinating investigator	Activation
Breast Cancer			
IBCSG 55-17 TOUCH	Phase II open-label, multicenter, randomized trial of neoadjuvant palbociclib in combination with hormonal therapy and HER2 blockade versus paclitaxel in combination with HER2 blockade for elderly patients with hormone receptor positive/HER2 positive early Brustkrebs 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 Brustkrebs cancer.	Stefan Paul Aebi	27.08.2019
Developmental Therapeutics			
BASILEA CDI-CS-002	An open-label Phase 1/2a study of oral BAL101553in adult patients with advanced solid tumors and in adult patients with recurrent or progressive glioblastoma or high-grade glioma.	Thomas Hundsberger	15.02.2021
BAY 1895344	A multicenter, non-randomized, open-label phase 1b study to determine the maximum tolerated and recommended phase 2 dose of the ATR Inhibitor BAY 1895344 in combination with pembrolizumab and to characterize its safety, tolerability, pharmacokinetics and preliminary anti-tumor activity in patients with advanced solid tumors.	Markus Jörger	14.04.2021
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 67/20	Open-label dose escalation phase 1b trial of a new micellar docetaxel compound in patients with metastatic castration-resistant prostate cancer	Ilaria Colombo	28.05.2021
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 Lymphom.	Markus Jörger	25.05.2018
Gastrointestinal Cancer			
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
Gynecological Cancer			
AGO-OVAR	Atezolizumab in combination with Bevacizumab +/- Chemotherapy versus Chemo-Bevacizumab standard in recurrent ovarian cancer – a randomised Phase III trial.	Christian Kurzeder	04.03.2021
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

Trial name	Trial title	Coordinating investigator	Activation
Leukemia			
CLL 17	A phase 3 multicenter, randomized, prospective, open-label trial of ibrutinib mono-therapy versus fixed-duration venetoclax plus obinutuzumab versus fixed-duration ibrutinib plus venetoclax in patients with previously untreated chronic lymphocytic leukemia (CLL).	Michael Gregor	16.12.2021
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
HOVON 155	A randomized phase II multicenter study to assess the tolerability and efficacy of the addition of midostaurin to 10-day decitabine in UNFIT (i.e. HCT-CI >= 3) adult AML and high risk myelodysplasia (MDS) (IPSS-R > 4.5) patients. A study in the frame of the masterprotocol of parallel randomized phase II studies in UNFIT- AML/high-risk MDS patients.	Sabine Blum	08.07.2021
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
Lung Cancer			
ACHILES	A randomized phase II study comparing atezolizumab after concurrent chemoradiotherapy with chemoradiotherapy alone in limited disease small-cell Lungenkrebs cancer.	Sacha Rothschild	29.01.2020
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 15/19	Thoracic radiotherapy plus maintenance Durvalumab after first line Carboplatin and Etoposide plus Durvalumab in extensive-stage disease small cell Lungenkrebs cancer (ED-SCLC). A multicenter single arm open label phase II trial.	Alfredo Addeo	24.06.2021
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 Lungenkrebs cancer (NSCLC). A multicenter single-arm phase II trial.		28.04.2020
SAKK 17/18	Overcoming Resistance to Immunotherapy combining Gemcitabine with atezolizumab in advanced NSCLC and mesothelioma progressing under immune-checkpoint inhibitors or gemcitabine. A multicenter, single-arm, open label phase II trial with two cohorts.	Alessandra Curioni-Fontecedro	02.03.2021
SAKK 19/17	First line durvalumab in patients with PD-L1 positive, advanced NSCLC with performance status 2 unsuitable for combination chemotherapy. A multicenter, single-arm phase II trial.	Michael Mark	23.10.2018

Trial name	Trial title	Coordinating investigator	Activation
Lymphoma			
HD 21	HD21 for advanced stages: Treatment optimization trial in the first-line treatment of advanced stage Hodgkin Lymphom; comparison of 4-6 cycles of escalated BEACOPP with 4-6 cycles of BrECADD.	Alden Moccia	29.03.2017
HOVON 127/ SAKK 37/16	Phase III study comparing R-CODOX-M/R-IVAC versus dose-adjusted EPOCH-R (DA-EPOCH-R) for patients with newly diagnosed high risk Burkitt Lymphom.	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 Lymphom.	Benjamin Kasenda	27.05.2019
IELSG-47	Phase II study of combination ibrutinib and rituximab in untreated marginal zone Lymphom.	Emanuele Zucca	13.02.2020
SAKK 38/19	Assessing a ctDNA and PET-oriented therapy in patients with DLBCL. A multicenter, open-label, phase II trial.	Anastasios Stathis	08.06.2021
Registries			
"SAKK 80/19 AlpineTIR"	Alpine Tumor Immunology Register.	Ulf Petrausch	06.02.2020
Urogenital Tumors			
SAKK 01/18	Reduced intensity radiochemotherapy for Stage IIA/B Seminoma. A multicenter, open label phase II trial with two cohorts.	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 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 2021

Studienname	Studientitel	Coordinating Investigator	Geschlossen
Developmental Therapeutics			
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 Lymphom.	Markus Jörger	25.08.2021
Gastrointestinal Cancer			
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	31.12.2021
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	22.04.2021
Leukemia			
HOVON 155	A randomized phase II multicenter study to assess the tolerability and efficacy of the addition of midostaurin to 10-day decitabine in UNFIT (i.e. HCT-CI >= 3) adult AML and high risk myelodysplasia (MDS) (IPSS-R > 4.5) patients. A study in the frame of the masterprotocol of parallel randomized phase II studies in UNFIT- AML/high-risk MDS patients.	Sabine Blum	15.11.2021
Lung Cancer			
ACHILES	A randomized phase II study comparing atezolizumab after concurrent chemoradiotherapy with chemoradiotherapy alone in limited disease small-cell Lungenkrebs cancer.	Sacha Rothschild	31.08.2021
Lymphoma			
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 Lymphom.	Frank Stenner	15.11.2021
Registries			
"SAKK 80/19 AlpineTIR"	Alpine Tumor Immunology Register.	Ulf Petrausch	25.11.2021
Urogenital Tumors			
SAKK 07/17	Nivolumab in combination with Ipilimumab in patients with metastatic renal cell carcinoma: A multicenter single-arm phase II trial.	Frank Stenner	07.06.2021
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	22.02.2021

Patient Numbers Per Disease and Member

Breast Cancer	Gastrointestinal Cancer	Gynecological Cancer	Head and Neck Cancer	Leukemia	Lung Cancer	Lymphoma	Melanoma	Supportive Care and Palliative Cancer Care	Urogenital Tumors	Totals	Member	Sites
45	**19**	**21**	**4**	**50**	**237**	**28**	**13**	**30**	**93**	**540**	**Member**	**Sites**
0	1	0	0	2	8	2	0	0	0	**13**	**Aargau**	Kantonsspital Aarau
0	0	0	0	0	2	0	0	0	0	**2**	**Baden**	Kantonsspital Baden
2	4	11	0	4	15	0	0	0	8	**44**	**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
0	0	0	0	14	9	7	0	1	2	**33**	**Bern**	Inselspital; Lindenhofgruppe – Engeriedspital; Lindenhofgruppe – Sonnenhofspital
0	0	0	0	0	0	0	0	0	0	**0**	**Biel**	Spitalzentrum Biel
2	2	0	0	0	2	0	1	0	5	**12**	**Claraspital**	Claraspital*
1	0	0	0	1	3	0	0	0	2	**7**	**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
1	0	0	0	2	15	0	0	1	0	**19**	**Genève**	Clinique des Grangettes; Hôpitaux Universitaires de Genève; Praxis Dr. med E. Tullen; Praxis Dr. med. A. Hügli
4	1	0	0	0	37	2	5	1	13	**63**	**Graubünden**	Kantonsspital Graubünden; Tumorzentrum ZeTuP Chur
7	9	2	0	0	38	1	4	5	15	**81**	**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
0	0	0	0	0	0	0	0	0	0	**0**	**Solothurn**	Bürgerspital Solothurn – Solothurner Spitäler; Kantonsspital Olten – Solothurner Spitäler
0	0	3	0	5	35	6	0	15	6	**70**	**St.Gallen**	Kantonsspital St.Gallen; Rundum Onkologie am Bahnhofpark; Tumor- und Brustzentrum ZeTuP; ZeTuP Rapperswil-Jona
0	0	0	0	0	2	0	0	0	0	**2**	**Thun**	Radio-Onkologie Berner Oberland AG; Spital STS AG Thun
2	0	2	0	0	0	0	0	0	1	**5**	**Thurgau**	Network – Spital Thurgau; Spital Thurgau - Kantonsspital Frauenfeld; Spital Thurgau – Kantonsspital Münsterlingen
3	2	0	4	4	37	4	3	5	4	**66**	**Ticino**	Clinica Luganese; EOC – Istituto Oncologico della Svizzera Italiana; Fondazione Oncologia Lago Maggiore; Oncologia Varini&Calderoni
1	0	0	0	0	0	0	0	0	2	**3**	**Valais**	Hôpital du Valais, Hôpital de Sion; Hôpital du Valais, Spital Brig; Network – Hôpitaux du Valais
1	0	0	0	2	3	0	0	0	1	**7**	**Vaud**	CCAC – Centre de Chimiothérapie Anti-Cancéreuse; CHUV – Centre hospitalier universitaire vaudois; Clinique de Genolier
10	0	0	0	0	4	1	0	0	0	**15**	**Winterthur**	Kantonsspital Winterthur
3	0	2	0	5	4	1	0	0	0	**15**	**Zentralschweiz**	Luzerner Kantonsspital Luzern
0	0	1	0	0	3	1	0	0	0	**5**	**Zürich Triemli**	Spital Limmattal; Stadtspital Triemli; Stadtspital Wald
0	0	0	0	11	20	3	0	2	8	**44**	**Zürich USZ**	Spital Männedorf; Universitätsspital Zürich
8	0	0	0	0	0	0	0	0	26	**34**	**Total Foreign Countries**	

* On 05.05.2021 the Claraspital became a SAKK member. Before that it was a site counting to the member Basel. Here the accrual is split between the two members based on the patient registration date.

Publications by SAKK and Cooperative Groups 2021

Trial name	Trial title	Authors	Journal	IF*
Breast Cancer				
IBCSG 18-98	Clinical behavior of recurrent hormone receptor-positive breast cancer by adjuvant endocrine therapy within the Breast International Group 1-98 clinical trial.	Leone JP, Cole BF, Regan MM, Thürlimann B, Coates AS, Rabaglio M, Giobbie-Hurder A, Gelber RD, Ejlertsen B, Harvey VJ, Neven P, Láng I, Bonnefoi H, Wardley A, Goldhirsch A, Di Leo A, Colleoni M, Vaz-Luis I, Lin NU.	CANCER	5.742
IBCSG 35-07	Continuous versus intermittent extended adjuvant letrozole for breast cancer: final results of randomized phase III SOLE (Study of Letrozole Extension) and SOLE Estrogen Substudy.	Jerusalem G, Farah S, Courtois A, Chirgwin J, Aebi S, Karlsson P, Neven P, Hitre E, Graas MP, Simoncini E, Abdi E, Kamby C, Thompson A, Loibl S, Gavilá J, Kuroi K, Marth C, Müller B, O'Reilly S, Gombos A, Ruhstaller T, Burstein HJ, Rabaglio M, Ruepp B, Ribi K, Viale G, Gelber RD, Coates AS, Loi S, Goldhirsch A, Regan MM, Colleoni M; SOLE Investigators	ANN ONCOL	32.976
IBCSG 52-15 PALLAS	Palbociclib with adjuvant endocrine therapy in early breast cancer (PALLAS): interim analysis of a multicentre, open-label, randomised, phase 3 study.	Mayer EL, Dueck AC, Martin M, Rubovszky G, Burstein HJ, Bellet-Ezquerra M, Miller KD, Zdenkowski N, Winer EP, Pfeiler G, Goetz M, Ruiz-Borrego M, Anderson D, Nowecki Z, Loibl S, Moulder S, Ring A, Fitzal F, Traina T, Chan A, Rugo HS, Lemieux J, Henao F, Lyss A, Antolin Novoa S, Wolff AC, Vetter M, Egle D, Morris PG, Mamounas EP, Gil-Gil MJ, Prat A, Fohler H, Metzger Filho O, Schwarz M, DuFrane C, Fumagalli D, Theall KP, Lu DR, Bartlett CH, Koehler M, Fesl C, DeMichele A, Gnant M.	LANCET ONCOL	41.316
SAKK 23/16	Implementation of Tailored Axillary Surgery for Patients with Clinically Node-Positive Breast Cancer: Prospective Study within SAKK 23/16, IBCSG 57-18, ABCSG-53, GBG 101.	Weber WP, Matrai Z, Hayoz S, Tausch C, Henke G, Zwahlen DR, Gruber G, Zimmermann F, Seiler S, Maddox C, Ruhstaller T, Muenst S, Ackerknecht M, Kuemmel S, Bjelic-Radisic V, Kurzeder C, Újhelyi M, Vrieling C, Satler R, Meyer I, Becciolini C, Bucher S, Simonson C, Fehr PM, Gabriel N, Maráz R, Sarlos D, Dedes KJ, Leo C, Berclaz G, Dubsky P, Exner R, Fansa H, Hager C, Reisenberger K, Singer CF, Reitsamer R, Reinisch M, Winkler J, Lam GT, Fehr MK, Naydina T, Kohlik M, Clerc K, Ostapenko V, Fitzal F, Nussbaumer R, Maggi N, Schulz A, Markellou P, Lelièvre L, Egle D, Heil J, Knauer M	THE BREAST	4.38

Trial name	Trial title	Authors	Journal	IF*
Gastrointestinal Cancer				
SAKK 40/00	Comparative surgical and oncological outcomes of upper rectal versus recto-sigmoid tumours: A systematic review and meta-analysis.	Morarasu S, O'Brien L, Clancy C, Dietrich D, Maurer C, Frasson M, Garcia-Granero E, Martin ST	EUR J SURG ONCOL	4.424
SAKK 41/06	Bevacizumab as maintenance therapy in patients with metastatic colorectal cancer: A meta-analysis of individual patients' data from 3 phase III studies.	Salvatore L, Bria E, Sperduti I, Hinke A, Hegewisch-Becker S, Aparicio T, Le Malicot K, Boige V, Koeberle D, Baertschi D, Dietrich D10, Tortora G, Arnold D	CANCER TREAT REV	3.619
Gynecological Cancer				
Mito/Mango 16b	Carboplatin-based doublet plus bevacizumab beyond progression versus carboplatin-based doublet alone in patients with platinum-sensitive ovarian cancer: a randomised, phase 3 trial.	Pignata S, Lorusso D, Joly F, Gallo C, Colombo N, Sessa C, Bamias A, Salutari V, Selle F, Frezzini S, De Giorgi U, Pautier P, Bologna A, Orditura M, Dubot C, Gadducci A, Mammoliti S, Ray-Coquard I, Zafarana E, Breda E, Favier L, Ardizzoia A, Cinieri S, Largillier R, Sambataro D, Guardiola E, Lauria R, Pisano C, Raspagliesi F, Scambia G, Daniele G, Perrone F	LANCET ONCOL	41.316
Head and Neck Cancer				
SAKK 10/94	Chemotherapy and radiotherapy in locally advanced head and neck cancer: an individual patient data network meta-analysis.	Petit C, Lacas B, Pignon JP, Le QT, Grégoire V, Grau C, Hackshaw A, Zackrisson B, Parmar MKB, Lee JW, Ghi MG, Sanguineti G, Temam S, Cheugoua-Zanetsie M, O'Sullivan B, Posner MR, Vokes EE, Cruz Hernandez JJ, Szutkowski Z, Lartigau E, Budach V, Suwinski R, Poulsen M, Kumar S, Ghosh Laskar S, Mazeron JJ, Jeremic B, Simes J, Zhong LP, Overgaard J, Fortpied C, Torres-Saavedra P, Bourhis J, Aupérin A, Blanchard P; MACH-NC and MARCH Collaborative Groups.	LANCET ONCOL	41.316
SAKK 10/94	Meta-analysis of chemotherapy in head and neck cancer (MACH-NC): An update on 107 randomized trials and 19805 patients, on behalf of MACH-NC group.	Lacas B, Carmel A, Landais C, Wong SJ, Licitra L, Tobias JS, Burtness B, Grazia Ghi M, Cohen EEW, Grau C, Wolf G, Hitt R, Corvò R, Budach V, Kumar S, Ghosh Laskar S, Mazeron JJ, Zhong LP, Dobrowsky W, Ghadjar P, Fallai C, Zaktonik B, Sharma A, Bensadoun RJ, Grazia Ruo Redda M, Racadot S, Fountzilas G, Brizel D, Rovea P, Argiris A, Takácsi Nagy Z, Lee JW, Fortpied C, Harris J, Bourhis J, Aupérin A, Blanchard P	RADIOTHER ONCOL	4.856

Trial name	Trial title	Authors	Journal	IF*
Leukemia				
HOVON 102	AML/Normal Progenitor Balance Instead of Total Tumor Load (MRD) Accounts for Prognostic Impact of Flowcytometric Residual Disease in AML.	Hanekamp D, Tettero JM, Ossenkoppele GJ, Kelder A, Cloos J, Schuurhuis GJ	CANCERS	6.639
HOVON 102	The added value of multi-state modelling in a randomized controlled trial: the HOVON 102 study re-analyzed.	Bakunina K, Putter H, Versluis J, Koster EAS, van der Holt B, Manz MG, Breems DA, Gjertsen BT, Cloos J, Valk PJM, Passweg J, Pabst T, Ossenkoppele GJ, Löwenberg B, Cornelissen JJ, de Wreede LC	CANCER MED	3.362
HOVON 103 - LEN	Effects of lenalidomide on the bone marrow microenvironment in acute myeloid leukemia: Translational analysis of the HOVON103 AML/SAKK30/10 Swiss trial cohort.	Brune MM, Stüssi G, Lundberg P, Vela V, Heim D, Manz MG, Haralambieva E, Pabst T, Banz Y, Bargetzi M, Grobholz R, Fehr M, Cogliatti S, Ossenkoppele GJ, Löwenberg B, Rudolf CB, Li Q, Passweg J, Mazzuchelli L, Medinger M, Tzankov A	ANN HEMATOL	2.904
HOVON 103 - TOS	Addition of the aminopeptidase inhibitor tosedostat to standard intensive treatment for elderly patients with AML and high risk MDS.	Janssen J, Löwenberg B, Manz M, Bargetzi M, Biemond B, Borne PVD, Breems D, Brouwer R, Chalandon Y, Deeren D, Efthymiou A, Gjertsen BT, Graux C, Gregor M, Heim D, Hess U, Hoogendoorn M, Jaspers A, Jie A, Jongen-Lavrencic M, Klein S, Klift MV, Kuball J, Lammeren-Venema DV, Legdeur MC, Loosdrecht AV, Maertens J, Kooy MVM, Moors I, Nijziel M, Obbergh FV, Oosterveld M, Pabst T, Poel MV, Sinnige H, Spertini O, Terpstra W, Tick L, Velden WV, Vekemans MC, Vellenga E, Weerdt O, Westerweel P, Stüssi G, Norden YV, Ossenkoppele G.	CANCERS	6.126
HOVON 132	Addition of lenalidomide to intensive treatment in younger and middle-aged adults with newly diagnosed AML: the HOVON-SAKK-132 trial.	Löwenberg B, Pabst T, Maertens J, Gradowska P, Biemond BJ, Spertini O, Vellenga E, Griskevicius L, Tick LW, Jongen-Lavrencic M, van Marwijk Kooy M, Vekemans MC, van der Velden WJFM, Beverloo B, Michaux L, Graux C, Deeren D, de Weerdt O, van Esser JWJ, Bargetzi M, Klein SK, Gadisseur A, Westerweel PE, Veelken H, Gregor M, Silzle T, van Lammeren-Venema D, Moors I, Breems DA, Hoogendoorn M, Legdeur MJC, Fischer T, Kuball J, Cornelissen J, Porkka K, Juliusson G, Meyer P, Höglund M, Gjertsen BT, Janssen JJWM, Huls G, Passweg J, Cloos J, Valk PJM, van Elssen CHMJ, Manz MG, Floisand Y, Ossenkoppele GJ.	BLOOD ADV	4.91

Trial name	Trial title	Authors	Journal	IF*
Lung Cancer				
	A cost-effectiveness analysis of pembrolizumab with or without chemotherapy for the treatment of patients with advanced non-small cell lung cancer and high PD-L1 expression in Switzerland.	Barbier MC, Pardo E, Panje CM, Gautschi O, Lupatsch JE	EUR J HEALTH ECON	2.367
ETOP BOOSTER	A randomised phase II study of osimertinib and bevacizumab versus osimertinib alone as second-line targeted treatment in advanced NSCLC with confirmed EGFR and acquired T790M mutations: the European Thoracic Oncology Platform (ETOP 10-16) BOOSTER trial.	Soo RA, Han JY, Dafni U, Cho BC, Yeo CM, Nadal E, Carcereny E, de Castro J, Sala MA, Bernabé R, Coate L, Pulla MP, Campelo RG, Cuffe S, Hashemi SMS, Früh M, Massuti B, Garcia-Sanchez J, Dómine M, Majem M, Sanchez-Torres JM, Britschgi C, Pless M, Dimopoulou G, Roschitzki-Voser H, Ruepp B, Rosell R, Stahel RA, Peters S; ETOP 10-16 BOOSTER Collaborators	ANN ONCOL	32.976
ETOP SPLENDOUR	Combined, patient-level, analysis of two randomised trials evaluating the addition of denosumab to standard first-line chemotherapy in advanced NSCLC – The ETOP/EORTC SPLENDOUR and AMGEN-249 trials.	Peters S, Danson S, Ejedepang D, Dafni U, Hasan B, Radcliffe HS, Bustin F, Crequit J, Coate L, Guillot M, Surmont V, Rauch D, Rudzki J, O'Mahony D, Barneto Aranda I, Scherz A, Tsourti Z, Roschitzki-Voser H, Pochesci A, Demonty G, Stahel RA, O'Brien M.	LUNG CANCER	3.958
SAKK 16/00	Impact of CT convolution kernel on robustness of radiomic features for different lung diseases and tissue types.	Denzler S, Vuong D, Bogowicz M, Pavic M, Frauenfelder T, Thierstein S, Eboulet EI, Maurer B, Schniering J, Gabrys HS, Schmitt-Opitz I, Pless M, Foerster R, Guckenberger M, Tanadini-Lang S.	BR J RADIOL	2.196
SAKK 16/00	Preselection of robust radiomics features does not improve outcome modelling in non-small cell lung cancer based on clinical routine FDG-PET imaging.	Oliveira C, Amstutz F, Vuong D, Bogowicz M, Hüllner M, Foerster R, Basler L, Schröder C, Eboulet EI, Pless M, Thierstein S, Peters S, Hillinger S, Tanadini-Lang S, Guckenberger M.	EJNMMI RESEARCH	2.73
SAKK 16/00	Quantification of spatial distribution of primary tumors in the lung to develop new prognostic biomarkers for locally advanced NSCLC.	Vuong D, Bogowicz M, Wee L, Riesterer O, Vlaskou Badra E, D'Cruz LA, Balermpas P, van Timmeren JE, Burgermeister S, Dekker A, De Ruysscher D, Unkelbach J, Thierstein S, Eboulet EI, Peters S, Pless M, Guckenberger M, Tanadini-Lang S.	SCI REP	4.379
SAKK 16/14	SAKK 16/14: Durvalumab in addition to neoadjuvant chemotherapy in patients with stage IIIA(N2) non-small cell lung cancer – A multicentre single-arm phase II trial.	Rothschild SI, Zippelius A, Eboulet EI, Savic Prince S, Betticher D, Bettini A, Früh M, Joerger M, Lardinois D, Gelpke H, Mauti LA, Britschgi C, Weder W, Peters S, Mark M, Cathomas R, Ochsenbein AF, Janthur WD, Waibel C, Mach N, Froesch P, Buess M, Bohanes P, Godar G, Rusterholz C, Gonzalez M, Pless M	J CLIN ONCOL	18.428
SAKK 19/16	Binimetinib, pemetrexed and cisplatin, followed by maintenance of binimetinib and pemetrexed in patients with advanced non-small cell lung cancer (NSCLC) and KRAS mutations. The phase 1B SAKK 19/16 trial.	Froesch P, Mark M, Rothschild SI, Li Q, Godar G, Rusterholz C, Oppliger Leibundgut E, Schmid S, Colombo I, Metaxas Y, König D, Sessa C, Gautschi O, Früh M	LUNG CANCER	3.958

Trial name	Trial title	Authors	Journal	IF*
Lymphoma				
HD 14	Intensified treatment of patients with early stage, unfavourable Hodgkin lymphoma: long-term follow-up of a randomised, international phase 3 trial of the German Hodgkin Study Group (GHSG HD14).	Gillessen S, Plütschow A, Fuchs M, Markova J, Greil R, Topp MS, Meissner J, Zijlstra JM, Eichenauer DA, Bröckelmann PJ, Diehl V, Borchmann P, Engert A, von Tresckow B.	LANCET HAEMATOL	10.406
HD 17	PET-guided omission of radiotherapy in early-stage unfavourable Hodgkin lymphoma (GHSG HD17): a multicentre, open-label, randomised, phase 3 trial.	Borchmann P, Plütschow A, Kobe C, Greil R, Meissner J, Topp MS, Ostermann H, Dierlamm J, Mohm J, Thiemer J, Sökler M, Kerkhoff A, Ahlborn M, Halbsguth TV, Martin S, Keller U, Balabanov S, Pabst T, Vogelhuber M, Hüttmann A, Wilhelm M, Zijlstra JM, Moccia A, Kuhnert G, Bröckelmann PJ, von Tresckow B, Fuchs M, Klimm B, Rosenwald A, Eich H, Baues C, Marnitz S, Hallek M, Diehl V, Dietlein M, Engert A.	LANCET ONCOL	41.316
HD 18	Impact of bone marrow involvement on PET-2 positivity and progression-free survival in the HD18 trial for patients with advanced-stage Hodgkin lymphoma	Kreissl S, Voltin CA, Kaul H, Bühnen I, Mettler J, Pabst T, Eichenauer DA, Fuchs M, Diehl V, Dietlein M, Engert A, Borchmann P, Kobe C.	BR J HAEMATOL	5.67
HD 18	PET-guided eBEACOPP treatment of advanced-stage Hodgkin lymphoma (HD18): follow-up analysis of an international, open-label, randomised, phase 3 trial.	Kreissl S, Goergen H, Buehnen I, Kobe C, Moccia A, Greil R, Eichenauer DA, Zijlstra JM, Markova J, Meissner J, Feuring-Buske M, Soekler M, Beck HJ, Willenbacher W, Ludwig WD, Pabst T, Topp MS, Hitz F, Bentz M, Keller UB, Kühnhardt D, Ostermann H, Hertenstein B, Aulitzky W, Maschmeyer G, Vieler T, Eich H, Baues C, Stein H, Fuchs M, Diehl V, Dietlein M, Engert A, Borchmann P	LANCET HAEMATOL	18.959
IELSG-42	MATRix-RICE therapy and autologous haematopoietic stem-cell transplantation in diffuse large B-cell lymphoma with secondary CNS involvement (MARIETTA): an international, single-arm, phase 2 trial.	Ferreri AJM, Doorduijn JK, Re A, Cabras MG, Smith J, Ilariucci F, Luppi M, Calimeri T, Cattaneo C, Khwaja J, Botto B, Cellini C, Nassi L, Linton K, McKay P, Olivieri J, Patti C, Re F, Fanni A, Singh V, Bromberg JEC, Cozens K, Gastaldi E, Bernardi M, Cascavilla N, Davies A, Fox CP, Frezzato M, Osborne W, Liberati AM, Novak U, Zambello R, Zucca E, Cwynarski K	LANCET HAEMATOL	10.406
SAKK 38/07	Cost-Effectiveness of Shortening Treatment Duration Based on Interim PET Outcome in Patients With Diffuse Large B-cell Lymphoma.	Greuter M, Eertink JJ, Jongeneel G, Dührsen U, Hüttmann A, Schmitz C, Lugtenburg PJ, Barrington SF, Mikhaeel NG, Ceriani L, Zucca E, Carr R, Györke T, Burggraaff CN, de Vet H, Hoekstra OS, Zijlstra JM, Coupé V; PETRA consortium	CLIN LYMPHOMA MYELOMA LEUK	3.231

Trial name	Trial title	Authors	Journal	IF*
SAKK 38/07	Generation and validation of a PET radiomics model that predicts survival in diffuse large B cell lymphoma treated with R-CHOP14: A SAKK 38/07 trial post-hoc analysis.	Ceriani L, Milan L, Cascione L, Gritti G, Dalmasso F, Esposito F, Pirosa MC, Schär S, Bruno A, Dirnhofer S, Giovanella L, Hayoz S, Mamot C, Rambaldi A, Chauvie S, Zucca E	HEMATOL ONCOL	3.084
SAKK 38/07	Optimal timing and criteria of interim PET in DLBCL: a comparative study of 1692 patients.	Eertink JJ, Burggraaff CN, Heymans MW, Dührsen U, Hüttmann A, Schmitz C, Müller S, Lugtenburg PJ, Barrington SF, Mikhaeel NG, Carr R, Czibor S, Györke T, Ceriani L, Zucca E, Hutchings M, Kostakoglu L, Loft A, Fanti S, Wiegers SE, Pieplenbosch S, Boellaard R, Hoekstra OS, Zijlstra JM, de Vet HCW	BLOOD ADV	4.91
Supportive Care and Palliative Cancer Care				
SAKK 95/16	RE:Real-World Use of Bone Modifying Agents in Metastatic Castration-Sensitive Prostate Cancer.	Mark M, von Moos R, Cathomas R, Stoffel A, Gillessen S	J Natl Cancer Inst	13.506
SAKK 95/16	Patterns of care and economic consequences of using bone-targeted agents for castration-sensitive prostate cancer patients with bone metastases to prevent skeletal-related events in Switzerland – the SAKK 95/16 prostate study.	Stoffel ST, von Moos R, Thürlimann B, Cathomas R, Gillessen S, Zürrer-Härdi U, von Briel T, Anchisi S, Feller A, Schär C, Dietrich D, Schwenkglenks M, Lupatsch JE, Mark MT	SWISS MED WKLY	1.821
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 (SAKK 95/16).	Ribi K, Thürlimann B, Schär C, Dietrich D, Cathomas R, Zürrer-Härdi U, von Briel T, Anchisi S, Bohanes P, Blum V, von Burg P, Mannhart M, Caspar C, Moos R, Mark M	ANN ONCOL	7.04
Urogenital Tumors				
SAKK 09/10	Dose-intensified versus conventional dose salvage radiotherapy for biochemically recurrent prostate cancer after prostatectomy: the SAKK 09/10 randomised phase 3 trial.	Ghadjar P, Hayoz S, Bernhard J, Zwahlen DR, Hölscher T, Gut P, Polat B, Hildebrandt G, Müller AC, Plasswilm L, Papachristofilou A, Schär C, Sumila M, Zaugg K, Guckenberger M, Ost P, Reuter C, Bosetti DG, Khanfir K, Gomez S, Wust P, Thalmann GN, Aebersold DM	EUR UROL	13.938
STAMPEDE	Abiraterone acetate and prednisolone with or without enzalutamide for high-risk non-metastatic prostate cancer: a meta-analysis of primary results from two randomised controlled phase 3 trials of the STAMPEDE platform protocol.	Attard G, Murphy L, Clarke NW, Cross W, Jones RJ, Parker CC, Gillessen S, Cook A, Brawley C, Amos CL, Atako N, Pugh C, Buckner M, Chowdhury S, Malik Z, Russell JM, Gilson C, Rush H, Bowen J, Lydon A, Pedley I, O'Sullivan JM, Birtle A, Gale J, Srihari N, Thomas C, Tanguay J, Wagstaff J, Das P, Gray E, Alzoueb M, Parikh O, Robinson A, Syndikus I, Wylie J, Zarkar A, Thalmann G, de Bono JS, Dearnaley DP, Mason MD, Gilbert D, Langley RE, Millman R, Matheson D, Sydes MR, Brown LC, Parmar MKB, James ND; Systemic Therapy in Advancing or Metastatic Prostate cancer: Evaluation of Drug Efficacy (STAMPEDE) investigators.	LANCET	79.321

* Impact factor

Presentation of SAKK Trials (Without Cooperative Groups)

American Association for Thoracic Surgery (AATS) Annual Meeting

Oral presentation

Schmitt-Opitz I. et al. Extended resections for advanced stages T3/T4 NSCLC including N2 disease after neoadjuvant treatment: results and conclusions of SAKK pooled analysis (16/96, 16/00, 16/01).

American Society of Clinical Oncology (ASCO) Annual Meeting

Poster discussion

Dal Pra A. et al. Validation of the Decipher Genomic Classifier (GC) in SAKK 09/10: A Phase III Randomized Trial of Dose Escalated Salvage Radiotherapy (SRT) after Radical Prostatectomy (RP).

Online publication

Addeo A. et al. Fibroblast growth factor receptor (FGFR) inhibitor rogaratinib in patients with advanced pretreated squamous-cell non-small cell lung cancer over-expressing FGFR mRNA: the SAKK 19-18 phase II study.

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

Oral presentation

Ghadjar P. et al. Dose-intensified versus conventional dose salvage radiotherapy for biochemically recurrent prostate cancer after prostatectomy: 6 year outcomes of the SAKK 09/10 randomized phase 3 trial.

Poster

Cathomas R. et al. Safety and efficacy of perioperative cisplatin/gemcitabine (cis/gem) and durvalumab (durva) for operable muscle-invasive urothelial carcinoma (MIUC): SAKK 06/17.

American Society of Hematology (ASH) Annual Meeting

Oral presentation

Eichhorst B. et al. A Randomized Phase III Study of Venetoclax-Based Time-Limited Combination Treatments (RVe, GVe, GIVe) Vs Standard Chemoimmunotherapy (CIT: FCR/BR) in Frontline Chronic Lymphocytic Leukemia (CLL) of Fit Patients: First Co-Primary Endpoint Analysis of the International Intergroup GAIA (CLL13) Trial.

Oral presentation

Fürstenau M. et al. High Resolution Assessment of Minimal Residual Disease (MRD) By Next-Generation Sequencing (NGS) and High-Sensitivity Flow Cytometry (hsFCM) in the Phase 3 GAIA (CLL13) Trial.

Poster

Eichenauer DA. et al. Treatment of Early-Stage Nodular Lymphocyte-Predominant Hodgkin Lymphoma: A Subgroup Analysis of the Randomized German Hodgkin Study Group HD16 Study.

Poster

Fuchs M. et al. PET-Guided Treatment in Patients with Early-Stage Favorable Hodgkin Lymphoma: Follow-up Analysis of the HD16 Trial By the German Hodgkin Study Group.

Poster

Fürstenau M. et al. Comparison of Tumor Lysis Syndrome (TLS) Risk Reduction and Incidence in Different Venetoclax-Based Combinations within the Randomized Phase 3 GAIA (CLL13) Trial.

American Society for Radiation Oncology (ASTRO) Annual Meeting

Oral presentation

Dal Pra A. et al. Performance of the Decipher Genomic Classifier (GC) within the SAKK 09/10 Phase 3 Randomized Trial of Dose Escalated Salvage Radiotherapy (SRT) after Radical Prostatectomy (RP).

Connective Tissue Oncology Society (CTOS) Annual Meeting

Oral presentation

Digklia A. et al.

SAKK 57/16 Nab-Paclitaxel and Gemcitabine in soft tissue sarcoma (NAPAGE): results from the phase Ib/II trial.

Jahrestagung der Deutschen Gesellschaft für Radioonkologie e.V. (DEGRO)

Oral presentation

Ghadjar P. et al. Dosiseskalation Salvage RT? Ergebnisse SAKK 09/10.

Jahrestagung der Deutschen Pharmazeutischen Gesellschaft e.V. (DPhG)

Poster

Schmulenson E. et al. Population pharmacokinetic analyses of regorafenib and capecitabine in patients with locally advanced rectal cancer (SAKK 41/16 RECAP).

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

Oral presentation

Attard G. et al. Abiraterone acetate plus prednisolone (AAP) with or without enzalutamide (ENZ) added to androgen deprivation therapy (ADT) compared to ADT alone for men with high-risk non-metastatic (M0) prostate cancer (PCa): Combined analysis from two comparisons in the STAMPEDE platform protocol.

Oral presentation

Cathomas R. et al. Darolutamide 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 (SAKK 08/16).

Oral presentation

Le Pechoux C. et al. An international randomized trial, comparing post-operative conformal radiotherapy (PORT) to no PORT, in patients with completely resected non-small cell lung cancer (NSCLC) and mediastinal N2 involvement: characterisation of PORT efficacy in the Lung ART study (IFCT-0503, UK NCRI, SAKK) NCT00410683.

Oral presentation

Papachristofilou A. et al. Single-dose carboplatin followed by involved-node radiotherapy as curative treatment for seminoma stage IIA/B: efficacy results from the international multicenter phase II trial SAKK 01/10.

Poster

Al-Batran S. et al. Pathological regression in patients with microsatellite instability (MSI) receiving perioperative atezolizumab in combination with FLOT vs. FLOT alone for resectable esophagogastric adenocarcinoma: Results from the DANTE trial of the German Gastric Group at the AIO and SAKK.

Poster

Joerger M. et al. Outcome and prognostic factors of COVID-19 infection in cancer patients: Final results of the SAKK 80/20 CaSA study.

Poster

Kopp C. et al. Frequency of PD-L1 positivity and microsatellite instability (MSI) in the DANTE trial: perioperative atezolizumab with FLOT versus FLOT alone in patients with resectable esophagogastric adenocarcinoma. A randomized, open-label phase IIb trial of the German Gastric Group at the AIO and SAKK.

Poster

Wicki A. et al. Anti-EGFR-immunoliposomes loaded with doxorubicin in patients with advanced triple negative, EGFR positive breast cancer – A multicenter single arm phase II trial [SAKK 24/14].

ESMO Immuno-Oncology Congress (ESMO IO)

Poster

König D. et al. Comparison of PD-L1 expression before and after neoadjuvant chemoradiation or chemotherapy in stage III non-small cell lung cancer (NSCLC).

The European Society for Radiotherapy and Oncology (ESTRO) Congress

Online publication

Vuong D. et al. Voxel-wise quantification of anatomical location of tumors in lung related to decreased overall survival.

International Conference on Malignant Lymphoma (ICML)

Oral presentation

Ceriani L. et al. Development and validation of a PET radiomics prognostic model for diffuse large B cell lymphoma.

Oral presentation

Genta S. et al. Integration of baseline metabolic parameters and mutational profile predicts outcome in DLBCL patients. A post hoc analysis of SAKK38/07 study.

Oral presentation
Novak U. et al. SAKK 36/13 – Ibrutinib plus bortezomib and ibrutinib maintenance for relapsed and refractory mantle cell lymphoma: final report of a Phase I/II trial of the European MCL network.

International Myeloma Workshop (IMW)
Poster
Zander T. et al. Alternate day dosing of pomalidomide in patients with refractory/relapsed multiple myeloma (RRMM): Results of a multicenter, single arm phase 2 trial (SAKK 39/16 OptiPOM Study).

Population Approach Group Europe (PAGE) Meeting
Poster
Schmulenson E. et al. Population pharmacokinetic analyses of regorafenib and capecitabine in patients with locally advanced rectal cancer (SAKK 41/16 RECAP).

Sarkomkonferenz der Deutschen Sarkom-Stiftung
Oral presentation
Digklia A. et al.
SAKK 57/16 Nab-Paclitaxel and Gemcitabine in soft tissue sarcoma (NAPAGE): results from the phase Ib/II trial.

Swiss Oncology and Hematology Congress (SOHC)
Oral presentation
Cathomas R. et al. Darolutamide maintenance in mCRPC previously treated with novel hormonal agents and non-progressive on taxane: randomized phase II trial (SAKK 08/16).

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

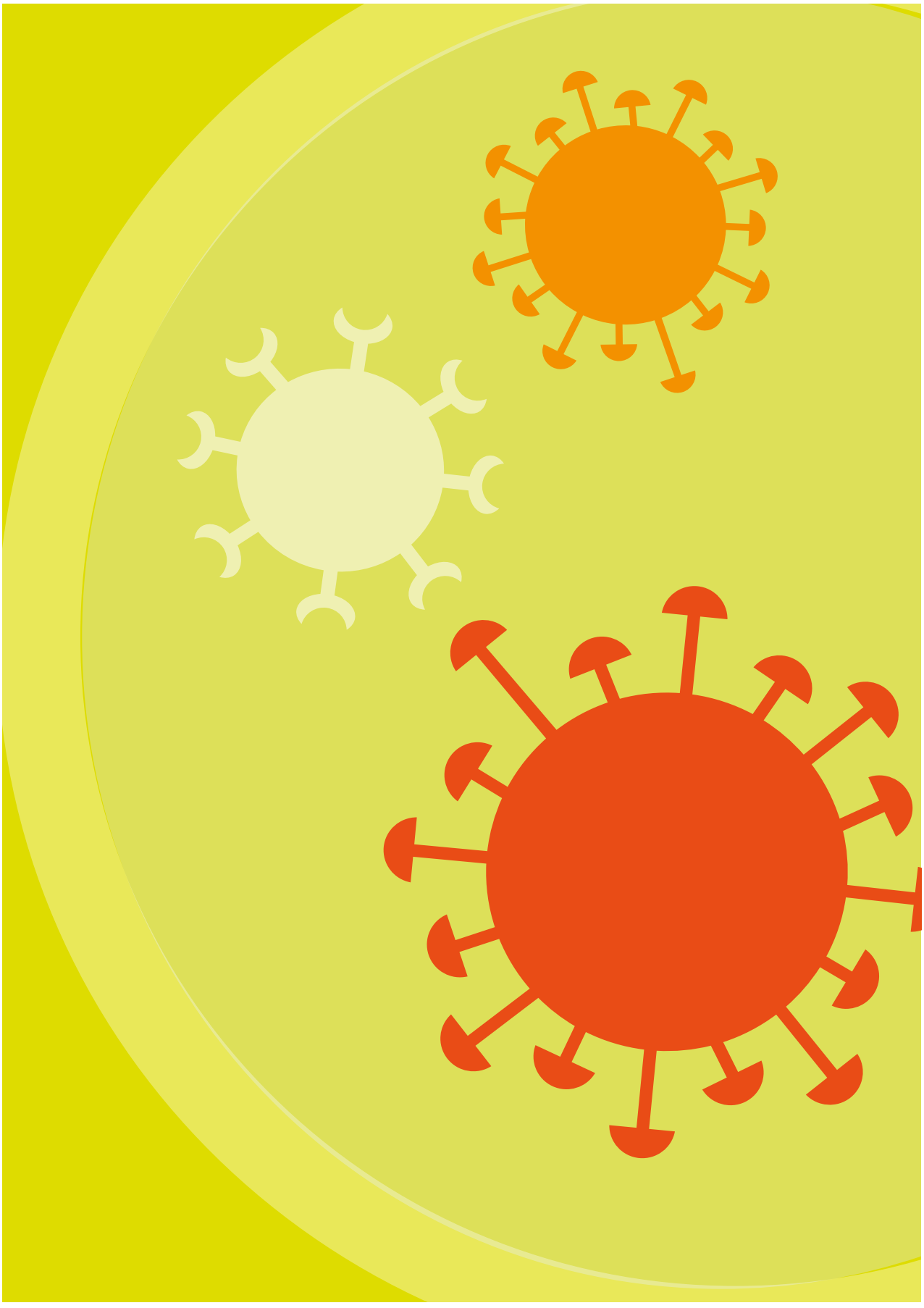
Oral presentation
König D. et al. Long-term outcomes of operable stage III NSCLC in the pre-immunotherapy era.

Oral presentation
Papachristofilou A. et al.
Single-dose carboplatin followed by involved-node radiotherapy in seminoma stage IIA/B: efficacy results from the international, phase II trial SAKK01/10.

Oral presentation
Rothschild S. I. et al. SAKK 16/14 – Association of tumour mutational burden with outcomes in patients with stage IIIA-NSCLC treated with neoadjuvant chemotherapy and durvalumab.

Poster
Rothschild S. et al. SAKK 16/14 – T-cell receptor repertoire metrics predict response to neoadjuvant durvalumab in patients with stage IIIA(N2) NSCLC.

IASLC World Conference on Lung Cancer (IASLC WCLC)
Oral presentation
Rothschild S. et al. SAKK 16/14 – T-cell receptor repertoire metrics predict response to neoadjuvant durvalumab in patients with stage IIIA(N2) NSCLC.



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