Annual report 2017

We want the best possible cancer therapy.

SAKK

WE BRING PROGRESS TO CANCER CARE

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Please note that for reasons of readability and accuracy, academic titles are not translated throughout this report. The most common (Swiss) titles correspond to the following English equivalents:
Dr. med. – Medical Doctor, Doctor of Medicine, MD
Dr. nat./Dr. phil. – PhD
PD – associate professor
Prof. – professor

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Content

Prof. Dr. med. Roger von Moos
SAKK President

Dr. sc. nat. Peter Brauchli
SAKK CEO

Dear Readers,
Dear Colleagues,

The market for trials is booming in the era of molecular oncology and immuno-oncology. There are very few companies that do not have a PD-1 or PDL-1 antibody in the pipeline, and tyrosine kinase inhibitors of BRAF, MEK, ALK and EGFR are being developed concurrently by several firms. The differences between the molecules are expected to be slight. The range of oncology drugs is becoming broader and more complex all the time and it will be essential to pick out the true innovations. This is why SAKK is intensifying its collaboration with start-up companies that are pursuing innovative ideas.

Manufacturers usually carry out trials of new pharmacologically active substances on their own, and it is becoming increasingly difficult for SAKK to develop investigator-initiated trials. At the same time, the effort and costs associated with trials of this kind are also growing, not least because of the manufacturers' requirements. The associated negotiations are also difficult, particularly if a combination therapy is the subject of a trial and the molecules come from different companies. In the past year, we nevertheless succeeded in developing a number of investigator-initiated trials in immuno-oncology.

SAKK must assert itself in this internationally competitive market and make the most of its strengths, which include quality and reliability. Close networking between the SAKK centers and their commitment to prioritizing SAKK trials will be vital in enabling SAKK to continue make progress in the therapy of patients in the future.

Centers face the challenge of having to resist the prevailing pressure on costs and make resources available for clinical research. In 2017 the SAKK centers received 20 % more funding for clinical trials. At the Coordinating Center in Bern procedures are reviewed on an ongoing basis and streamlined wherever possible. This enables us to retain a lean cost structure and to remain competitive.

At the Board retreat in May, SAKK defined its strategic priorities and the associated actions for the coming years. One focus is the promotion of upcoming young scientists to ensure the transfer of expertise. The Young Oncology Academy is one of the fundamental components of the Young Investigator Initiative YII. The program was organized for the third time in 2017, with seven participants from three disciplines completing it successfully. Read more about it on page 14.

Our trial portfolio grew in 2017 – mostly with early phase I and major phase III trials with potential impact on future therapy management. A total of 1265 patients were enrolled in the trials we coordinated, the highest number in ten years. A bigger portfolio makes us attractive for both small and large centers in our network.

The referral system introduced in 2016 is making good progress. A total of 31 patients from 16 hospitals and practices were referred to other hospitals so that they could take part in a clinical trial. This is a major success, and our thanks go to everyone who supported this project. Detailed figures are given on page 52.

It is against this background that we and you can feel optimistic about the future, and we are confident of achieving the goals that we have set ourselves. We would like to thank everyone who contributes to the success of SAKK and who will continues to support us for the benefit of patients.

Prof. Dr. med.
Roger von Moos
SAKK President

Dr. sc. nat.
Peter Brauchli
SAKK CEO

Claudia Herren / Communications Manager

March

15th St. Gallen International Breast Cancer Conference

Experts from major cooperative groups and centers working in clinical research, basic research and clinical management of breast cancer present their latest data at the St. Gallen Breast Cancer Conference in Vienna. SAKK is an official partner of the Conference and is represented by experts in Vienna.

3rd Swiss Lung Cancer Symposium

The Swiss Lung Cancer Symposium takes place in Bern on 23 March. This conference focuses on the latest developments in the therapy of lung cancer. It gives participants the opportunity to share views with experts and Swiss colleagues, ask questions and discuss best practices.

June

SAKK presents news from the ASCO annual meeting

The annual meeting of the American Society of Clinical Oncology (ASCO) is held in Chicago from 2 to 6 June. PD Dr. med. Thomas Ruhstaller presents the trial SAKK 75/08 in the Poster Discussion session and PD Dr. med. Markus Jörger presents a poster of trial SAKK 67/15 Basilea in the trials in progress session (read more on page 59).

The **Swiss PostASCO** event is held for the 11th time in Bern on 22 June. A number of speakers explain the scientific findings from the ASCO annual meeting to an expert audience.

SAKK summer semi-annual meeting

The semi-annual meeting takes place in Zurich in late June. The General Assembly on 28 June 2017 elects Prof. Dr. med. Stefan Breitenstein as a new member of the SAKK Board. He is Director of the Department of Surgery and Head of the Visceral and Chest Surgery Clinic at the Cantonal Hospital Winterthur.

Public event focusing on breast cancer research

During the semi-annual meeting the SAKK Patient Advisory Board organizes the first ever public event on the topic of breast cancer research. Renowned experts in the field of oncology give presentations at the event. Read more on page 16.

Life Grant 2017 for research into pancreatic cancer

This year's Life Grant is awarded to PD Dr. med. Martin Maurer from University Hospital Bern (Inselspital) for his research project "Impact of Diffusion-weighted Magnetic Resonance Imaging to Evaluate Treatment Response of Patients undergoing Neoadjuvant Therapy with Borderline Resectable or Locally Advanced Pancreatic Carcinoma". The Life Grant is awarded jointly by SAKK and Celgene for planned or ongoing research projects focusing on the therapy of pancreatic cancer.

Prof. Dr. med. Oliver Gautschi wins the SAKK / Pfizer Award 2017

Prof. Gautschi from the Cantonal Hospital Lucerne wins the SAKK / Pfizer Award 2017 for his publication "Targeting RET in Patients With RET-Rearranged Lung Cancers: Results from the Global, Multicentre RET Registry".

The SAKK / Dr. Paul Janssen Fellowship 2017 enables a young scientist to pursue further training abroad

This year's SAKK / Dr. Paul Janssen Fellowship is awarded to Dr. med. Christoph Ackermann from the Cantonal Hospital St. Gallen. He will use the Fellowship to undertake a research period at the Christie National Health Service Foundation Trust in Manchester (UK).

September

Orphan Malignancies Seminar 2017

On 1 September 2017 this year's Orphan Malignancies Seminar is held on the subject of "Immunotherapy as a 'panacea' for rare tumors – can its use be optimized?" It is chaired by PD Dr. med. Richard Cathomas and PD Dr. med. Frank Stenner. The seminar is held under the patronage of SAKK.

BAUM at the Race for Life – fighting cancer with sport and music

BAUM, the musician from Basel, takes part in the charity bicycle marathon Race for Life in Bern for the second time on 3 September 2017. As a SAKK ambassador, Baum has been supporting the battle against cancer for nearly two years. This year, however, he is not only cycling in the marathon as part of the SAKK team; he is also performing with his band on the Bundesplatz during the Race for Life solidarity festival.

October

European MCL Network Symposium

The annual meeting of the European NCL Network is held in Chur on 26 and 27 October under the patronage of SAKK. At the symposium, experts discuss the therapy of mantle-cell lymphomas and therapeutic options with new, innovative drugs.

November

SAKK winter semi-annual meeting

500 specialists from the SAKK network and representatives of the pharmaceutical industry meet in Zurich on 23 and 24 November. The SAKK General Assembly meets the evening before and elects Prof. Dr. med. et phil. Olivier Michielin and Prof. Dr. med. Emanuele Zucca as new members of the SAKK Board. Prof. Dr. med. Zucca replaces Prof. Dr. med. Cristiana Sessa, who has left the Board following her retirement, as the representative for the Italian-speaking part of Switzerland.

Prizes awarded at the SAKK semi-annual meeting

The SAKK / Amgen Research Grant and the SAKK / Astellas GU Oncology Award are once again presented at the semi-annual meeting of SAKK held on 23 November 2017.

This year's SAKK / Amgen Research Grant goes to Dr. med. et phil. nat. Sara Christina Meyer from Basel University Hospital (Hematology) in recognition of her translational research project titled "Targeting therapeutic resistance to novel JAK2 inhibitors in myeloproliferative neoplasms".

The SAKK / Astellas GU Oncology Award 2017 goes to Prof. Dr. med. Jean-Philippe Theurillat from the Cancer Research Institute (IOR) in Bellinzona. The prize of CHF 30,000 is awarded to Prof. Theurillat for his exceptional scientific paper on "Opposing effects of cancer type-specific SPOP mutations on BET protein degradation and sensitivity to BET inhibitors".

December

Federal funding for a personalized oncology project

The personalized oncology project initiated by the University Hospital Lausanne (CHUV) and in collaboration with SAKK and the University Hospitals Geneva (HUG), receives substantial federal funding. With support from the federal government, the Swiss Personalized Health Network (SPHN) initiative provides CHF 2.3 million for the project, which aims at networking molecular and clinical data from a large majority of cancer patients in Switzerland.

Clinical trials as an opportunity to receive therapy?

Claudia Herren, Communications Manager

It is a scenario that no-one would want to encounter. There is no authorized drug to help the lung cancer patient – neither chemotherapy nor radiotherapy can stop the cancer from growing. The doctor suggests one final possibility: participation in a trial with a new drug. It is the patient's last chance – but it may also constitute a risk.

The lung cancer patient is fortunate that his oncologist has suggested taking part in a trial. There are fewer and fewer trials being run in Switzerland. The small market and the low patient numbers are of little interest to some pharmaceutical companies. Moreover, the legal situation in Switzerland has a reputation for making trials difficult and research unattractive.

An active network helps patients

Active networking of oncologists plays an important role and benefits patients too. The President of the lung cancer project group, PD Dr. med. Martin Früh, mentions the example of atezolizumab, a new immunotherapy developed by Roche to treat lung cancer. This study was initiated with a drug that became available in 2013, initially on a trial basis. Fifteen patients took part; "five of them are alive today. And they are very well," despite the initially poor prognosis. Experts regularly discuss new therapy options within the SAKK network and this enables them to provide their patients with detailed information about trials they can take part in.

Three phases of trial conduct

In a narrower sense, clinical cancer research is conducted over three phases that vary both in terms of their aims and applied procedure. Each new phase depends and builds on the preceding phase. The criteria for participation in a trial in certain phases depend on various factors such as the progression of the disease, previous treatments, and the general condition of the respective patient, among others.

Phase I: Is the new treatment safe?

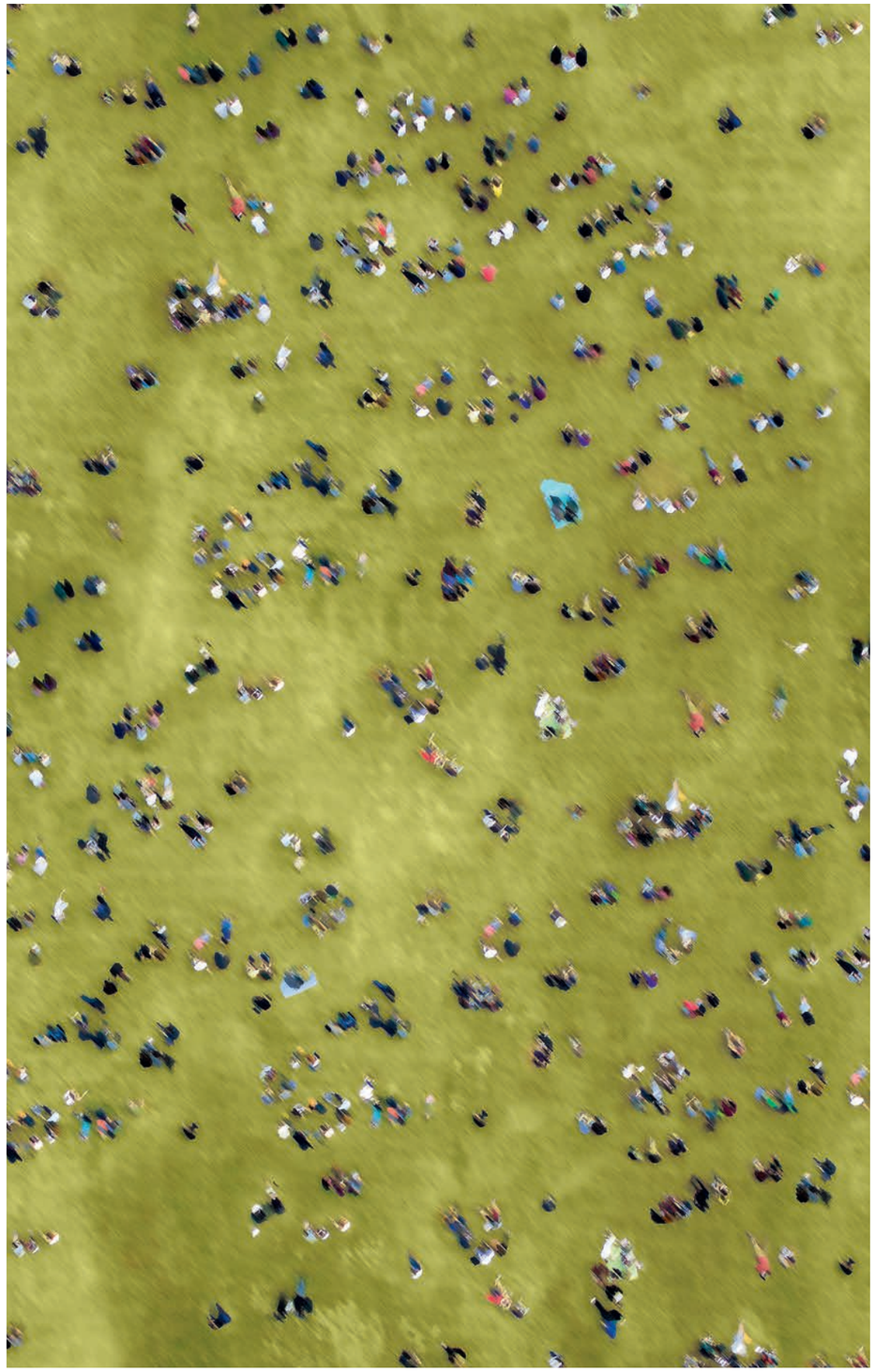
In this phase, tests which were previously only conducted in a laboratory or on animals are now performed on humans in order to find new treatment methods ("first-in-human"). Also, phase I trials may investigate new combinations of existing, effective treatments or examine new indications of approved therapies. In general, only up to 30 patients are included. The trial is designed to show that a treatment is safe, which harmful side effects may appear, and how a drug is absorbed, distributed and broken down in the body. Ultimately, one aims at finding the best possible drug administration and dosage for the new treatment. With respect to phase I trials for cancer drugs, only patients are accepted who suffer from a disease for which there is no therapy, or for which standard therapies have shown to not be effective. Healthy individuals cannot be included in trials for cancer treatments.

Phase II: Is the new treatment effective?

Phase II trials assess the effectiveness and tolerability of a treatment against a specific type of cancer in the defined dosage. Only 30 to 200 patients are included. Also, phase II trials investigate druf safety and monitors all metabolic activity. Phase III follows once a treatment method has proven to be well-tolerated and effective.

Phase III: Does the treatment have any advantages compared to existing therapies?

In a phase III trial, a new treatment is compared to a conventional method, a standard or best-practice therapy in order to determine potential advantages of the new treatment, e.g. improved tumor response, longer survival rate, decreased side effects or improved quality of life. Phase III trials may include hundreds or even thousands or participants at different hospitals and research centers in various countries. For a sound and significant statistical analysis, high-quality data is required from a particular number of participants. This is a prerequisite for evaluating the results in terms of which treatment is best for the patients. Once a drug has been tested in phase III, the results usually serve as a basis for an application for approval with the relevant authorities.



Phase IV: Optimizing the therapy
After market approval, rare side effects and interactions with other drugs are observed in order to optimize the drug and to tailor it to different diseases and patients' individual circumstances. Through phase IV, the investigated treatment becomes a recognized standard therapy in the battle against cancer.

For certain tumors or diseases, however, there are no standard therapies as of yet. In these cases, one patient group may be administered the new drug, for example, while the other group receives none. In any case, no patient is denied a treatment or drug which has proven to be effective. This would be unethical. Patients who are randomly assigned to the group which does not receive the new medication are occasionally offered the new drug if the standard therapy does not have an effect (anymore). This is called a cross-over trial.

An interview with our CEO Peter Brauchli on the topic:

According to Interpharma, an organization representing the interests of the research-based pharmaceutical industry, the number of clinical trials in all indications has almost halved in Switzerland since 2006. The trend is evident in all trial phases. What is the likely reason for this?
This development is paradoxical. On the one hand, the existing types of cancer are increasingly being divided into subcategories in oncology and a growing number of new drugs are being tested. The growing number of diseases and new active substances ought to lead to a larger number of clinical trials being performed. Since this is not happening, progress is being slowed down.

The main reason is that greater demands are being placed on the performance of trials. They now require more administrative effort and, as a result, a greater financial outlay. The outcome of this development started to become evident a long time ago: the pharmaceutical industry is carrying out clinical trials in Asia and Eastern Europe, where the costs are lower. We are also seeing an increase in the cost of trials that are not funded by the pharmaceutical industry. But this increase has not been matched by an increase in funding from foundations, public sources or health insurance providers.

Some sources say that the legal requirements in this country inhibit research and make trials more difficult. The Human Research Act came into effect in 2014. Has the situation improved since then?
Basically not much has changed for the better since then. The entire process of registering trials with the authorities has become faster on average and some procedures have been streamlined; but at the same time, the enactment of the Human Research Act has increased the required administrative effort required. The number of documents needed to submit a trial has increased greatly, and even minimal changes require complex modifications.

How do you explain the fact that in Switzerland relatively few patients perceive trials as an opportunity for treatment?
Patients often don't know much about this option. Oncology centers and hospitals still don't have much incentive to enroll patients in clinical trials. Clinical trials basically mean more work for the hospitals, and this is not compensated for by scientific kudos. This situation means that there are few trials available for patients.

What is SAKK doing to strengthen Switzerland as a research base and to enable more patients to take part in trials?
SAKK has started the "referrals" project, for example, in which patients are referred to other hospitals where they can take part in a trial. A total of 31 patients were referred in 2017. Often only a few hospitals enroll patients, particularly in phase I trials, since they can be more problematic. We are also working with the Swiss Cancer League on a project to increase the involvement of general practitioners. GPs often have a close relationship with their patients and can inform them about possible treatment options. SAKK has recently started trying to influence the legislative process with the aim of having the research viewpoint included when laws are revised. The recently established Patient Advisory Board also gives patients a voice. There is more information about this on page 16.

The interview was conducted by Jacqueline Schwerzman, Swiss Radio and Television SRF: https://www.srf.ch/news/panorama/studien-fuer-krebspatienten-last-exit-versuchskaninchen

Young Oncology Academy

Sara Probst / Communications Manager

Successful continuation and expansion of the Young Oncology Academy
SAKK held the Young Oncology Academy, a program designed to promote and mentor young oncologists, for the third time in 2017. The Academy is part of the SAKK Young Investigators Initiative, which sets out to counter the decline in numbers of clinical scientists by offering various initial and further training activities.

Insight into clinical and translational research
The Young Oncology Academy targets junior doctors at the start of their medical career who have a clear focus on cancer medicine. The Academy started with four participants in its first year, and in 2017 the program was expanded to include radio-oncology and hematology. Its third iteration welcomed seven successful candidates.

The participants in the 2017 Academy were each mentored by a renowned faculty member of the Young Oncology Academy for almost a year. The emphasis was particularly on giving the talented young scientists insight into the successful development, management, implementation and publication of a clinical trial. As part of the Academy, the participants also attended the ESMO, EHA (for haematologists) or ESTRO (for radio-oncologists) congress.

Networking at the SAKK semi-annual meeting
In addition to focusing on oncological expertise and knowledge, the young oncologists also took part in various courses designed to hone editorial and presentation skills. They were able to display the latter at the SAKK semi-annual meeting in November, where they gave their final presentations to an audience of experts at the Post-ESMO/EHA/ESTRO Symposium. The upcoming oncologists were also introduced formally to the project groups and had the opportunity to network in their field and make contacts useful for their future career.

Young Oncology Academy 2018
Evaluation of the satisfaction survey showed that the participants were very satisfied with the program offered in the Academy 2017 and highly recommend participation to their colleagues. The program will therefore be offered again in the same form in 2018 with generous support from Bayer (Switzerland) AG, Takeda and Merck (Switzerland) AG.

SAKK Patient Advisory Board

Sara Probst / Communications Manager

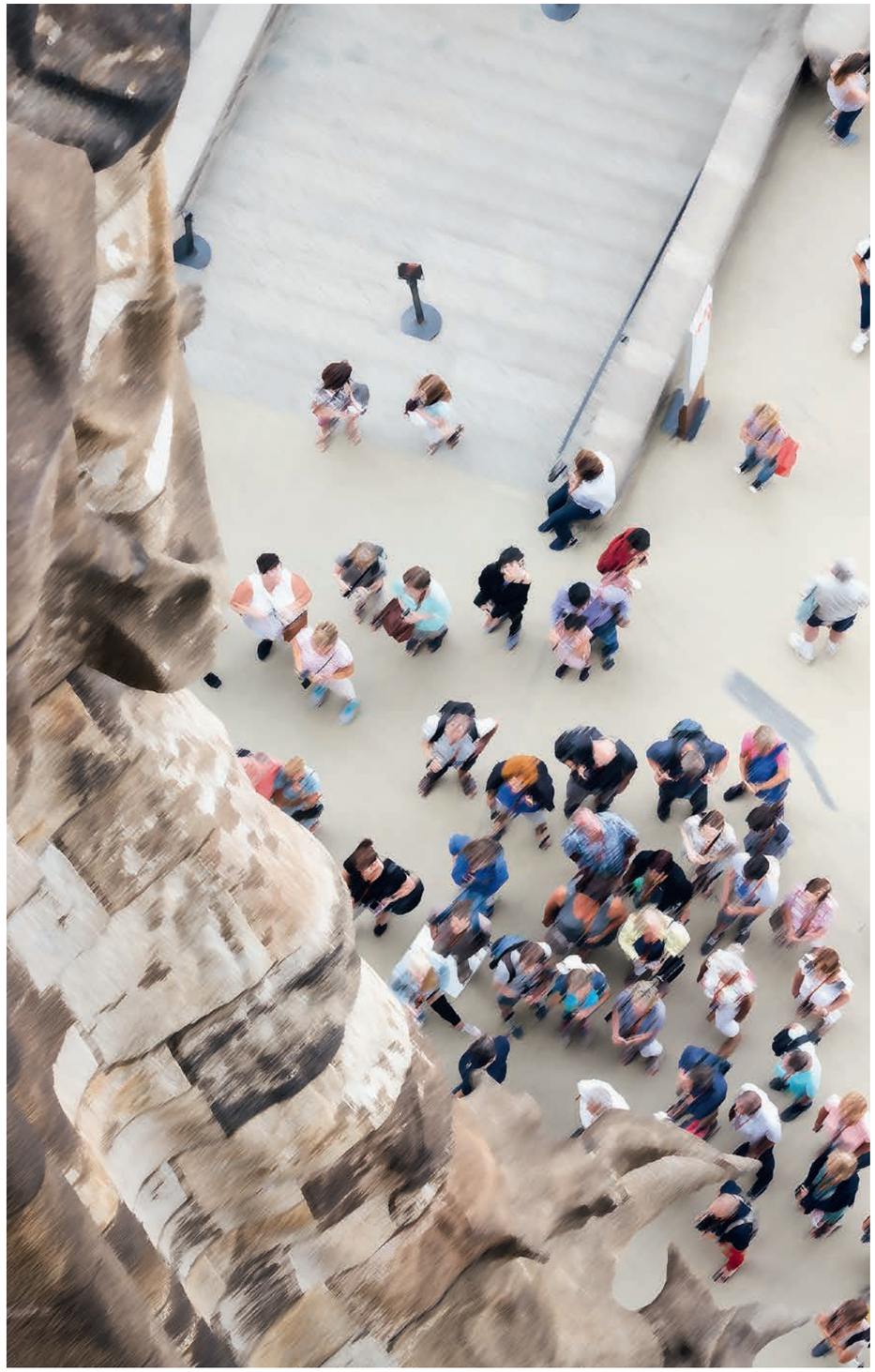
Activities to date and future development
SAKK set up the Patient Advisory Board in November 2015 with the aim of gaining a better understanding of the experiences and needs of cancer patients and their families and using this information to inform its research projects. The board, which currently has five members, has been actively advising SAKK for two years on three levels: strategy, trial development and communication. The support provided by the Patient Advisory Board enabled us to achieve important progress on all three levels in 2017.

Improving patient information and establishing a strategy
In 2017, Patient Advisory Board was involved closely in the development and finalization of patient information, one aspect of trial development. The board proposed important modifications of the wording for seven new trials; this substantially improved the readability and clarity of the documents. The aim is also to submit a number of proposals for optimizing the document templates directly to Swissethics by mid-2018. In October the five members were trained in various aspects of clinical research to enable them to play their role in trial development even more effectively in 2018.

Easily accessible online information and patient forum
The SAKK website is a central means of ensuring that patients and their families are provided with timely and transparent information about ongoing trials. Here, too, the Patient Advisory Board made some valuable suggestions for improvements that were implemented in 2017. The required information about a trial can be found quickly using a search function, and now the names of contacts at the centers and hospitals are provided as well. Information about the board, its function and the members is now displayed more prominently on the website. These online communication activities will be continued and optimized in 2018.

At the board's suggestion, the "get-together for cancer patients" organized by OncoCampus Switzerland was integrated into the SAKK semi-annual meeting. This patient forum was held for the first time in June, when it focused on the topic "diagnosed with breast cancer" and was met with great interest. The event entitled "diagnosed with lymphoma" was equally well – received in November. In addition to providing a platform for presentations by experts on the current status of clinical research, the patient forum is also intended to provide an occasion for patients to put their questions to the experts and talk to each other.

Patient guidance – a central value now and in the future
Close contact with cancer patients and patient organizations is vital for the further development of new and improved cancer therapies that seek to improve the chance of a cure and patients' quality of life. In May 2017, the SAKK Board resolved at the strategic level to further strengthen the position of the Patient Advisory Board by 2020 and to specifically promote its activities over the coming years.



Project Group Breast Cancers

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

The project group had to bid farewell to Thomas Ruhstaller as President, who stepped down after two terms in this function. He succeeded in winning the collaboration of breast surgeons, radiooncologists and pathologists and leading the group to true interdisciplinarity. This was the basis for the conduct of the first surgical trial, SAKK 23/13, for which patients were recruited quickly, and the results of which will be presented at the Annual Cancer Symposium of the Society of Surgical Oncology in 2018. The next surgical trial – the European Axilla Study (SAKK 23/16 TAXIS) – is a huge undertaking, developed and lead by our group with the participation of foreign sites: accrual should start in 2018.

Of course we still have an emphasis on conventional cancer drug trials: we conduct both our own SAKK trials and take part in large international trials with cooperative groups like the International Breast Cancer Study Groups IBCSG and BIG. A further interest of our group are "out-of-the-box trials" that focus on examining the efficacy of medical and non-medical interventions to reduce the burden of side effects of anticancer treatments for our breast cancer patients.

In 2017 our group accrued a total of 253 patients (of which 171 were recruited in our own SAKK trials and 82 patients in international trials). This number is indeed slightly lower than in 2016 (283 patients), but now the vast majority of patients are enrolled in intervention trials. We expect higher numbers for 2018 because the European Axilla Study will be open for accrual, and patient recruitment for SAKK 96/12 (REDUSE), which was our highest accruing trial 2017, will be ongoing.

There was an initiative to involve smaller hospitals and some oncologists in private practice in order to enlarge our accrual base. As a consequence, there are now 37 Swiss sites which contribute patients to SAKK 96/12 (REDUSE) and 26 sites for SAKK 25/14 (Eribulin in elderly patients with metastatic breast cancer).

Project Group Gastrointestinal Cancers

President: Dr. med. et phil. Andreas Wicki,
University Hospital Basel

Accrual numbers of the group have been rising, moving from 33 accrued patients in 2016 to 72 in 2017. This is mainly due to the successful activation of a number of trials in the last two years. In particular, the PRODIGE 32 study (surgery vs. surveillance in esophageal cancer after complete response to chemoradiotherapy) and the SAKK 41/16 trial (neoadjuvant chemoradiotherapy with regorafenib and capecitabine in rectal cancer) were activated in 2017 and are recruiting well.

SAKK 41/13 (adjuvant aspirin in colorectal cancer) and 41/14 (physical therapy in colorectal cancer patients in the palliative setting) are ongoing and the number of active centers has increased in 2017. Both trials have the potential to set new clinical standards and they are recruiting in Switzerland and international partner centers.

In 2017, Prof. Dr. med. Heinz-Josef Lenz stepped back as advisor. The group thanks Prof. Lenz for his intense and successful support of the group. The new advisor is Prof. Dr. med. Florian Lordick, head of the department of oncology at the University of Leipzig and acting president of the EORTC gastrointestinal group. The group welcomes Prof. Lordick and looks forward to a close and fruitful collaboration.

One focus 2018 will be the identification and set-up of new trials in the field of gastric and pancreatic cancer. To this end, the contacts with the European Organization for Research and Treatment of Cancer EORTC and the German Arbeitsgemeinschaft für Internistische Onkologie AIO have been intensified and a series of projects is actually being evaluated. A second focus will be the introduction of trials with immunotherapy in gastrointestinal cancers and the development of a corresponding SAKK pipeline in collaboration with the immunooncology group.

Project Group Leukemia

President: PD Dr. med. Georg Stüssi,
Oncology Institute of Southern Switzerland (IOSI) Bellinzona

With 150 patients in 2017, the accrual of the project group leukemia reached a record number, despite the fact that the protocol for young AML patients was closed (HOVON 132) in summer 2017, after having accrued almost 1000 patients throughout Europe.

The next trial generation will fundamentally change our approach to patients with AML. While previously all AML patients were treated within the same trial ("one fits all"), the HOVON-SAKK consortium has decided to move towards targeted therapy approaches in the future. Therefore, a timely screening for molecular alterations has to be guaranteed and patients will be included in different trials according to their molecular profile. As a consequence, the number of patients included in a specific protocol will decrease and these future trials have to be carried out in even larger international study collaborations.

The HOVON 135 trial for unfit elderly AML patients was very successful in 2017. The accrual was faster than expected, showing that clinical protocols are highly needed in this patient group that is difficult to treat. In 2018 the trial will have achieved the required patient number and the HOVON-SAKK consortium is currently developing the successor protocol.

In 2017, the CLL 13 trial also opened for first-line treatment in fit CLL patients. This large international phase III study compares the current standard treatment (FCR/BR) with different combinations of new and highly efficient CLL drugs. The trial will accrue almost 1000 patients and has the potential of fundamentally changing the current practice for this patient group.

Project Group Lung Cancer

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

Broad portfolio of SAKK trials in thoracic malignancies

Since 1996, one of our main focuses has been on multimodality treatment of stage III non-small cell lung cancer. The SAKK 16/08 study was introduced as an oral presentation at the ESMO meeting 2017. The currently open and well-accruing SAKK 16/14 trial for operable stage III patients is one of the first trials to investigate the feasibility and role of neoadjuvant immunotherapy followed by postoperative immunotherapy in this group of patients. Later in 2017, we were able to successfully complete accrual for SAKK 15/12, which investigated early whole brain irradiation in patients with extensive stage SCLC. First results from this study are eagerly awaited. The phase I SAKK 19/16 trial investigating two doses of the MEK inhibitor binimetinib in combination with first line cisplatin and pemetrexed in KRAS mutated, metastatic non-small lung cancer patients opened in four phase I SAKK centers in Switzerland. With up to 30 % of patients, KRAS mutations represent the largest molecular subgroup, and yet no targeted therapy has shown to be active to date. Therefore, referral of patients to participate in this trial is strongly encouraged. In mesothelioma, we have successfully opened the SAKK 17/16 trial, with lurbinectidin as a therapeutic option as second line treatment. SAKK 17/16 is a single arm phase II trial with participation of centers from Northern Italy. For the first time in 2018, the SAKK lung group

will be opening a study in patients with a poor performance status (PS2): SAKK 19/17 is a single arm phase II trial evaluating the efficacy and safety of durvalumab as first line therapy in PD-L1 positive metastatic non-small cell lung cancer patients with a PS of 2.

Strong international collaboration
Cooperation with international partners, mainly the European Thoracic Oncology Platform (ETOP) and the European Organisation for Research and Treatment of Cancer (EORTC), continues, particularly involving large phase III trials and rare thoracic tumor entities or molecular subsets. Currently open for accrual are the EORTC PEARLS adjuvant trial, testing the role of adjuvant pembrolizumab in resected non-small cell lung cancer; the EORTC Lung ART trial, which evaluates the role of adjuvant radiotherapy in resected N2 non-small cell lung cancer; and the ETOP SPLENDOUR, evaluating the activity of denosumab in stage IV non-small cell lung cancer. All three are large phase III trials. In addition, the ETOP PROMISE-meso study is another phase II trial in mesothelioma. In this trial, patients who failed cisplatin-based first line therapy are randomized into a pembrolizumab or a chemotherapy arm with the option of x-over. In addition, accrual has started for ETOP BOOSTER, a randomized trial addressing the role of bevacizumab in addition to osimer-tinib in T790M+ patients after first or second-generation EGFR tyrosin kinase inhibitors. Further protocols in subsets of lung cancer patients that will be opening in a limited number of centers in Switzerland and for which referral is strongly encouraged are ETOP Nivothym (nivolumab in B3 thymoma and thymic carci-noma) and ETOP ALERT (Alectinib in RET positive lung cancer). Both are planned for 2018. Further collaborative trials planned for 2018 include EORTC HALT, which is a randomized trial addressing the role of RT in patients with oligo-progression on TKIs for oncogene-addicted lung cancer.

We are dedicated to keeping our strategy focused on both SAKK trials within Switzerland as well as a strong collaboration with European cooperative groups, the SAKK working group molecular oncology and the project group new anticancer treatments.

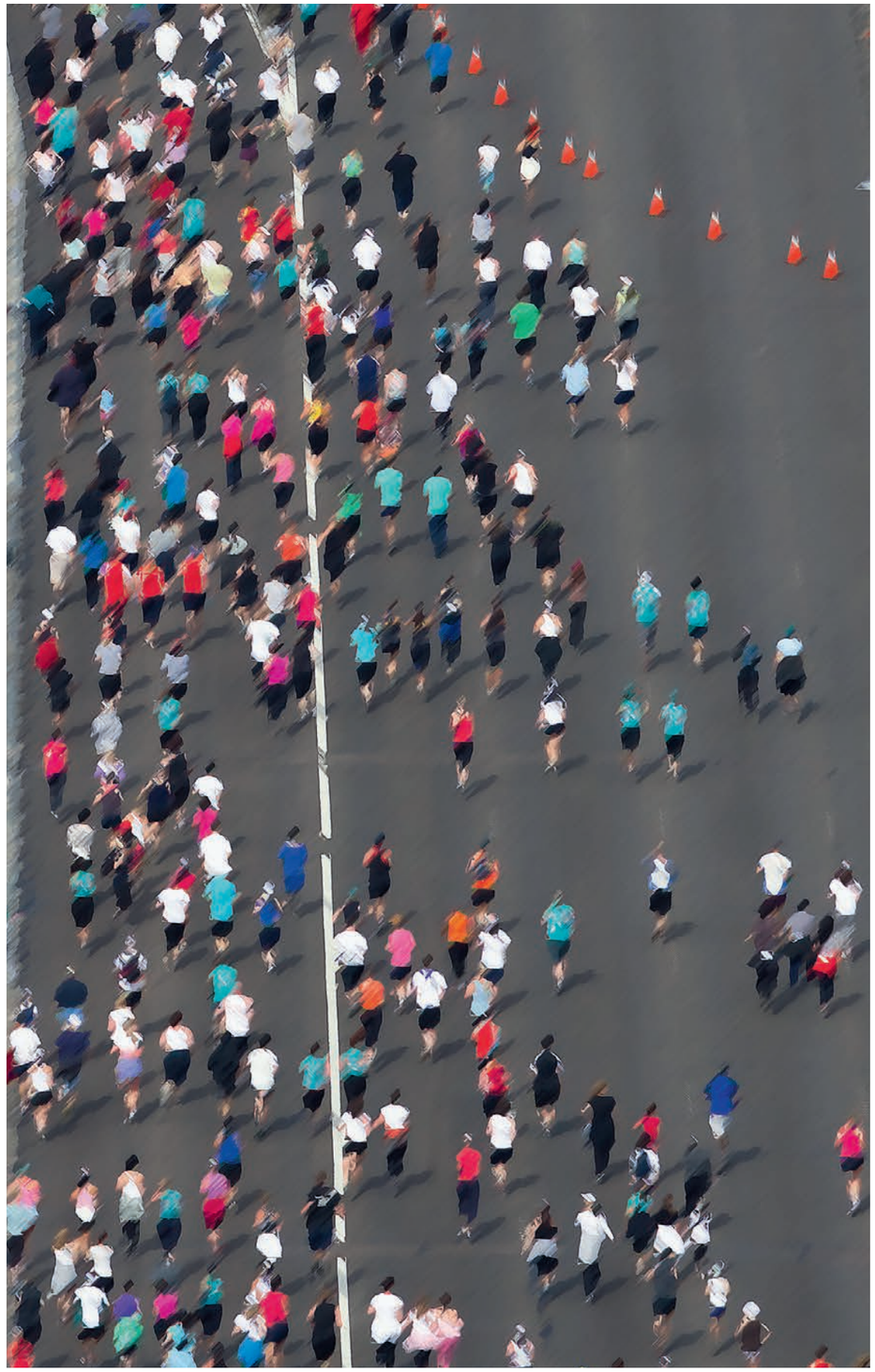
Project Group Lymphoma

President: PD Dr. med. Urban Novak, University Hospital Bern
Vice-President: Dr. med. Francesco Bertoni, Institute of Oncology Research / Oncology Institute of Southern Switzerland (IOSI), Bellinzona

In 2017, the results of the HD 18 trial were finalized and presented during the Presidential Symposium at the 22nd Congress of the European Hematology Association (EHA). With a significant contribution by our group, this pivotal trial revealed that patients with advanced Hodgkin Lymphoma do not need more than 4 cycles of chemotherapy to achieve an excellent outcome. Most importantly, the reduction decreases both short and long-term side effects. This achievement has been transferred to the current HD21 trial, which explores the antibody drug conjugate brentuximab vedotin in the experimental arm and continues our fruitful collaboration with the German Hodgkin Study Group.

In addition to the IELSG-37 trial, which challenges the need for a consolidation radiotherapy for patients with primary mediastinal lymphoma responding well to induction chemotherapy, our group will soon offer trials for lymphoma patients with primary or secondary central nervous system involvement (IELSG-42 and IELSG-43), mantle cell lymphoma (TRIANGLE), and, for the first time, a trial for Burkitt lymphoma (HOVON 127/SAKK 37/16). The latter, a collaboration with the HOVON group, is the courageous and purely academic endeavor to compare the European R-CODOX-M/R-IVAC with the American DA-EPOCH-R regimen. Altogether, these are all trials for rare entities for which our group will implement the referral system within our established network.

In order to have competitive trials for the larger body of our patients, we are currently developing a first-line trial for patients with diffuse-large B-cell lymphomas and, in collaboration with cardiologists, for lymphoma patients treated with cardiotoxic agents and radiotherapy to the chest. Alongside a new elegant academic trial, aiming to lower the treatment costs for patients with relapsed multiple myeloma, we are also working on the design of a



new first-line trial for patients suffering from this disease. In view of the rapidly evolving field, this is not an easy task.

The current main duty of our group is to complete the accrual of the two first-line trials for follicular lymphoma (SAKK 35/14 & SAKK 35/15) and of the relapsed mantle-cell lymphoma trial (SAKK 36/13).

Project Group New Anticancer Treatments

President: PD Dr. med. et rer. nat. Markus Jörger,
Cantonal Hospital St.Gallen
Vice-President: Dr. med. Anastasios Stathis,
Oncology Institute of Southern Switzerland (IOSI), Bellinzona

The SAKK project group new anticancer treatments has a broad focus on innovation in oncology. The current clinical trials and pipeline include early clinical development of conventional cytotoxics, molecularly-targeted agents, immunotherapeutics, as well as medical devices. The group had a major success in 2017 with the approval of two clinical trials evaluating the combination of the oral proteasome inhibitor ixazomib in combination with nelfinavir in patients with double-refractory myeloma (SAKK 39/17) and selected advanced solid tumors (triple-negative breast cancer and kidney cancer, SAKK 65/17). Similarly, negotiations on a clinical trial with a GSK3a/b inhibitor (LY2090314) in patients with advanced melanoma have been initiated, based on data generated in the laboratory of Dr. O. Shakhova.

In 2017, the project group opened four clinical trials:
- **SAKK 35/15,** a trial which is performed in collaboration with the lymphoma group, combines the BCL2-inhibitor venetoclax with the CD20-targeting monoclonal antibody obinutuzumab in treatment-naïve patients with advanced follicular lymphoma. The study is actively enrolling patients and will be opened also in selected centers in Germany.
- **SAKK 41/16** adds the multi-tyrosine kinase inhibitor regorafenib to capecitabine and radiotherapy in patients with locally advanced rectal cancer. SAKK 41/16 has successfully proceeded to the second dosing step without dose-limiting toxicity.
- **SAKK 11/16** explores early clinical activity of the personalized, cell-based antitumor immunization with MVX-ONCO-1, a combination of subcutaneous irradiated autologous tumor cells and encapsulated allogeneic cells engineered to release GM-CSF in patients with advanced squamous-cell cancer of the head and neck. This trial has been activated but has not started patient recruitment due to requirements of additional preclinical data by Swissmedic.
- Finally, **SAKK 19/16** assesses the safety and early clinical activity of the addition of the MEK-inhibitor binimetinib to standard first-line chemotherapy with cisplatin and pemetrexed in patients with KRAS-mutant advanced non-small cell lung cancer (NSCLC). The latter is a field of high unmet medical need as KRAS is the most frequent driver mutation in NSCLC, yet lacks efficient targeted systemic treatment. SAKK 19/16 has successfully proceeded to the second dosing step without dose-limiting toxicities as of yet.

In addition, the group has an ongoing trial, SAKK 67/15. Dose escalation with BAL-101553 has successfully been completed, with 70mg/m^2 being defined as the recommended phase-2 dose (RP2D), with central-nervous toxicity and hyponatremia occasionally observed at the higher dose levels.

Importantly, the trial portfolio is further improving. After activating the above-mentioned trials in 2017, several other trials are expected to open in 2018 and two clinical trials have been prepared in collaboration with the working group Immuno Oncology. Including the two collaborative studies, the project group expects to have up to 14 open clinical trials by the end of 2018. The group is strongly committed to collaborations with the other project groups and working groups, and in fact all ongoing or planned clinical trials include such collaborations.

The NAT project group is increasingly benefiting from the system of patient referals that has recently been introduced at SAKK. The concept supports referral of study patients to another hospital. Major goals of the group for the coming three-year period include the consolidation of a broad and innovative clinical trials pipeline, and further support trial sites to increase their capacity to run early-stage clinical trials within the SAKK network.

Project Group Urogenital Tumors

President: PD Dr. med. Richard Cathomas,
Cantonal Hospital Graubünden
Vice-President: PD Dr. med. Cyrill Rentsch,
University Hospital Basel

In January 2017, the third **"Translational Resarch Day in Urological Oncology"**, organized by our group, took place in Bern. Over 40 basic and clinical researchers from all of Switzerland gathered for a very informative and fruitful meeting focusing on translational science in the field of urogential tumors.

2017 was again very successful as the group managed to maintain its high accrual and was the highest recruiting SAKK project group for the third year in a row. In total, over 472 patients were included in the nine open SAKK trials from our group.

Three new trials opened in 2017: one randomized study for localized prostate cancer examining the impact of metformin on salvage radiotherapy (SAKK 08/15); another randomized trial investigates maintenance treatment with the novel antiandrogen ODM-201 for pretreated metastatic castration resistant prostate cancer (SAKK 08/16); and finally, the first SAKK trial in many years for metastatic renal cell carcinoma opened in December, studying the combination immunotherapy with ipilimumab and nivolumab with innovative design and extensive translational research.

The trial portfolio now includes nine trials in all different types of uro-oncology: five different prostate cancer trials and one trial each for renal cell carcinoma, bladder cancer, and testis cancer.

Two papers reporting interim results from the salvage radiotherapy trial SAKK 09/10 were published. Moreover, from the STAMPEDE study, the main results of the abiraterone arm were published in the New England Journal of Medicine.

In 2018, our trial portfolio will be further enhanced by a perioperative trial for localised muscle-invasive urothelial carcinoma using an immuno-oncology/chemotherapy combination (SAKK 06/17). The focus of the group remains on improving interdisciplinarity in all fields of genitouronary tumors and to conduct clinically relevant trials, including sound translational research.

Working Group Central Nervous System Tumors (CNS)

President: PD Dr. med. Patrick Roth,
University Hospital Zurich
Vice-President: Prof. Dr. med. Philippe Schucht,
University Hospital Bern

Neuro-oncology is a highly specialized field involving various disciplins. The major aim of the group is to strengthen the neuro-oncological community in order to improve the care of brain tumor patients in Switzerland.

Several members of the working group CNS tumors contributed to the amendment of the protocol of the SAKK 67/15 trial. The amended study will allow the enrolment of patients with progressive glioblastoma in the near future at several sites. Furthermore, the members of the working group have been closely involved in the development and organization of the "Swiss Glioma Network", which aims at setting up a database of glioma patients. Several clinically oriented research projects have been initiated involving various disciplines and centers in Switzerland.

As a next step, the group aims at participating in more clinical trials under the umbrella of SAKK. The strong involvement of several group members in international activities in neuro-oncology will help to achieve this goal and to further strengthen the position of the group. Therefore, a major focus in the next years will be to improve access to clinical trials for brain tumor patients in Switzerland as well as the design and organization of own clinical trials for patients with CNS malignancies within the SAKK network.

Working Group Head and Neck Cancers

President: Dr. med. Marco Siano, Cantonal Hospital St. Gallen

The group successfully activated two new trials:
The SAKK 10/16 trial in collaboration with EORTC, a large phase III European collaboration assessing the "best of radiotherapy" compared to the "best of surgery" (trans-oral surgery (TOS) in patients with T1-T2, N0 oropharyngeal carcinoma.

In the SAKK 11/16 trial we are investigating whether the immunotherapy MVX-ONCO-1 is effective, safe and tolerable in cases of advanced squamous cell carcinoma of the head and neck area. This immunotherapy consists of dead tumor cells from the patient and genetically modified cells in a capsule. For this, the patient's own tumor cells are removed, killed in a laboratory, and processed into a vaccine. This is then administered during the treatment. The immune system reacts to it and forms antibodies against the tumor cells, which helps the immune system to attack and destroy the tumor itself. The genetically modified cells release adjuvants which additionally stimulate the immune system. The trial is carried out in collaboration with the biotech company MaxiVAX SA, who won the 2017 CTI Swiss Medtech Award for this innovative vaccine project in June 2017, as part of Swiss Medtech Day.

Projects for the near future are, among others, an outcome research project about nivolumab in second line treatment and its cost-effectiveness, or the ARES-II trial combining an innovative induction regimen and a dose-escalation for subsequent neck radiotherapy. Furthermore, we joined forces with the EORTC Head and Neck Group for future involvement, study planning and exchange.

Working Group Imaging in Diagnostics and Therapy Monitoring

President: Dr. med. Prof. Hendrik von Tengg-Kobligk, University Hospital Bern
Vice-president: Prof. Dr. med. et sc. hum. Andreas Boss, University Hospital Zurich

Imaging in Diagnostics and Therapy Monitoring is an SAKK working group that operates across trials. Radiologists and experts in nuclear medicine from a number of Swiss hospitals contribute their experience in their specialist fields, thus supporting all SAKK trials that require imaging by evaluating image-based trial endpoints. In 2017 alone, the radiologists and experts in nuclear medicine in this working group were involved in 12 SAKK trials, enabling trial-compliant imaging and high-quality quantitative analysis to be performed in the respective hospitals.

The president is keen to ensure that tumor assessment is performed uniformly in SAKK trials. Accordingly, appropriate guidelines are developed during working group meetings to bring a greater degree of standardization to responsibilities and workflow aspects of oncological imaging. The aim of these guidelines is to address current and future quality issues relating to the analysis, documentation and communication of trial parameters, thus facilitating the non-invasive comparability of the therapies being investigated, for example.

This working group enables the experiences of various Swiss hospitals with radiological imaging to be discussed and standardized, as this technology is an essential tool for quantification of patient-oriented research. In order to meet the requirements of clinical cancer research, the members of the working group each focus on different organs and can thus provide the SAKK working groups and project

groups with their specific expertise. This is why a member of the Imaging working group is always present at the meetings of the other groups. And it explains why the semi-annual meetings are so important for the Working Group Imaging in Diagnostics and Therapy Monitoring in enabling it to input options and skills relating to oncological imaging into the trial planning process at an early stage.

Working Group Immuno Oncology

President: Prof. Dr. med. et phil. George Coukos,
University Hospital Vaud (CHUV) and University of Lausanne
Vice-Presidents: PD Dr. med. Ulf Petrausch,
Oncology Center Zurich – Klinik im Park
Dr. med. Alexandre Theocharides, University Hospital Zurich, Hematology
Prof. Dr. med. Alfred Zippelius, University Hospital Basel

In the wake of the robust development of immunotherapeutic approaches in cancer care, our newly founded Working Group Immuno Oncology emerged as a necessary addition to the SAKK research organigram; it aims at fostering and coordinating partnerships with universities, start-ups and industry partners to successfully combine local expertise in translational research with the advantages in patient recruitment provided by the collaboration with SAKK.

Of the 16 trials activated by SAKK in 2017, only six investigate immunotherapeutics and only one investigates an innovative compound, highlighting substantial opportunities for clinical research. The working group has received multiple collaboration proposals from diverse stakeholders in cancer immunotherapy, leading to developments of two upcoming protocols investigating intra-tumoral Toll-like receptor nine agonist therapy with PD-1 checkpoint blockade in metastatic melanoma and in locally advanced or metastatic triple-negative breast cancer.

Of special interest to the working group, cell-based immunotherapy approaches represent unique academic and clinical opportunities, yet rely on substantial infrastructure requirements hampering their availability. With this in mind, our longer-term strategic objectives will include the development of nation-wide cell-based therapies within the SAKK framework.

Working Group Molecular Oncology

President: PD Dr. med. et phil. Sacha Rothschild,
University Hospital Basel

After the foundation of this working group in 2016 with the aim of fostering personalized health care for cancer patients in Switzerland, 2017 was characterized by the establishment of a network of motivated experts. The group currently has 51 members and is an interdisciplinary network of medical oncologists, pathologists, molecular biologists, and hematologists. The group established a strong collaboration with the project group new anticancer treatments and the working group immuno-oncology, with joint sessions during the semi-annual meeting.

A first project that has been successfully finalized is a recommendation statement on next generation sequencing (NGS) reports. Within a small working team, NGS reports from most of the pathology institute performing sequencing analysis in clinical routine were collected. Based on those and on personal communication with the responsible molecular pathologists and medical oncologists, a recommendation statement was established. This recommendation consists of two main parts: in a first part, mandatory components of an NGS report are defined and recommendations on methodology, interpretation, and how this information should be provided in a report are specified. A second part lists optional components of an NGS report. This paper was distributed among Swiss pathologists, and after revisions all involved parties agreed on the recommendations. Thereafter, these recommendations were discussed and accepted by the members of the working group molecular oncology. Publication of this recommendation statement is currently in preparation. We believe that this recommendation statement helps to improve the quality of NGS reporting in Switzerland.

The aim for 2018 is to initiate a first clinical trial. Several projects with a focus on comprehensive molecular testing and early phase clinical trials are currently under discussion.

Working Group Sarcoma

President: Dr. med. Christian Rothermundt,
Cantonal Hospital St. Gallen

In 2017, the GeDDis trial was published in Lancet Oncology. This randomized controlled phase III trial assessed gemcitabine and docetaxel versus doxorubicin as first-line treatment in previously untreated advanced unresectable or metastatic soft-tissue sarcomas. The trial concluded that doxorubicin should remain the standard first-line treatment for most patients with advanced soft-tissue sarcoma (see publication on page 57). Currently, there are four clinical trials in development focusing on or incorporating sarcomas:

- Trial SAKK 57/16 (NAPAGE), a multicenter open-label single arm phase Ib/IIa trial investigating nab-paclitaxel and gemcitabine in advanced soft-tissue sarcoma.
- PazoQoL or GISG 11 is a collaboration with the German Interdisciplinary Sarcoma Group (GISG). This randomized controlled trial assesses quality of life in patients with soft-tissue sarcoma receiving either palliative chemotherapy or pazopanib. Patient reported outcomes (PROs) will be obtained electronically on an iPad.
- SAKK 66/17 (inCVAX), a multicenter open-label phase Ib trial with expansion cohorts to explore interstitial laser and intratumoural 1 % N-dihydrogalacto-chitosan (GC) injection in patients with laser-accessible, advanced solid tumors.
- EURO EWING 2012: An international randomised controlled trial for the treatment of newly diagnosed Ewing's sarcoma family of tumors.

We are excited about these promising activities within the small group of sarcoma experts and hope the trials will accrue patients as expected.

Working Group Supportive and Palliative Cancer Care

President: PD Dr. rer. med. Manuela Eicher,
University Hospital Vaud (CHUV) and University of Lausanne
Vice-Presidents: Dr. phil. Karin Ribi,
International Breast Cancer Study Group IBCSG
Dr. Gudrun Theile, University Hospital Zurich

In November 2016, the group elected a new president, Manuela Eicher, associate professor at the University of Lausanne, together with two vice-presidents, Karin Ribi, and Gudrun Theile.

The field of supportive and palliative cancer care offers a number of potential topics, including supportive and palliative care interventions, geriatric oncology, psycho-oncology, and cancer rehabilitation. The group discussed the strategy and potential topics to be addressed within the next two years, such as the integration of supportive and palliative care topics in SAKK trials (e.g. quality of life, geriatric oncology) developed by other groups, structured patient reported toxicity monitoring, geriatric oncology and others. It was decided that the focus should be on cancer care with prioritization of one or two key studies within the next two years, while remaining open for innovative trials related to any of the broader topics also including non-cancer diseases.

The group activated SAKK 95/16, a cross-sectional survey study to describe patterns of care for patients with metastatic bone disease in solid tumors in Switzerland.

Two projects are being developed with the goal to submit at least one of them to the SAKK Board by the end of 2018. The first project is a planned phase II trial investigating a patient-needs-based multi-professional delivery of palliative interventions by cancer clinicians (oncologists and oncology nurses). The second project aims at improving the understanding of the treatment experience and quality of life of cancer patients undergoing immune check-point inhibitor therapy, and to investigate potential associations between symptoms and immune-related biomarkers by combining quantitative with qualitative data.

Section Pathology

President: Prof. Dr. med. Rupert Langer, Institute of Pathology, University of Bern

The Section Pathology views itself as a diagnostic and scientific platform that seeks to offer support particularly in translational research associated with clinical trials. At the same time it initiates and runs its own projects in close collaboration with the organ-specific working groups and project groups. It is also involved in the quality assurance of pathological diagnoses in clinical trials, compliance with pre-analytical and analytical standards in tissue-based analysis, the application and introduction of new analytical methods and the establishment, operation and maintenance of tissue banks. The section also works closely with the Swiss Society of Pathology (SGPath) and its organ-specific working groups.

Section Radio-oncology

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

Establishing a consistent radiotherapy-quality assurance program for all clinical trials

The section supports clinical and translational trials in all organ groups, in 2017 predominantly in the head and neck, the lung, the gastrointestinal, and the urogenital groups. Trials questioning the value of radiation therapy in comparison to surgery have been activated or designed, as in early oropharyngeal (SAKK 10/16-EORTC 1420 "Best-Of"), in locally advanced oesophageal (PRODIGE 32 – ESOSTRATE 1 – FFCD 1401), and in node-positive breast cancer (SAKK 23/16 "TAXIS") within international collaborations.

The basis of all modern trials is a new, consistent but pragmatic and affordable SAKK program in radiation quality assurance to guarantee comprehensible, reasonable, transferable and reproducible results of trials using radiation therapy, to be subsequently used in clinical routine. This QA program is foreseen to be utilized in all future trials, as well.

Network for Cancer Predisposition Testing and Counseling CPTC

President: PD Dr. med. Sheila Unger, University Hospital Vaud (CHUV)

In 2017, the Network CPTC was active in several areas relating to the care of individuals with a genetic predisposition to cancer. A new visual aid was developed to help professionals with counseling for hereditary breast and ovarian cancer, and this aid should be widely available in 2018. It will help to harmonize counseling practices across Switzerland and a corresponding patient brochure is in development. In collaboration with the Swiss Society of Senology, the breast imaging available for hereditary breast-ovarian cancer syndromes (HBOC) has been revised and submitted to the Federal Office of Public Health. An official course is now available for physicians and other health professionals interested in developing their counseling skills. In 2018, the CPTC network will work on several projects, but a priority will be making a position statement on the efficacy of panel testing and concurrent revisions to the list of analyse.

Network for Outcomes Research

President: Dr. med. Konstantin Dedes, University Hospital Zurich

The network published a manuscript regarding the cost-effectiveness of palbociclib plus letrozole versus letrozole alone as a first-line treatment in women with oestrogen receptor-positive, HER2-negative, advanced breast cancer and finalized the cost minimization analysis alongside the SAKK trial 23/13. In addition, two literature-based cost-effectiveness studies were finalized and are expected to be published in 2018. The network has a new researcher, Judith Lupatsch, as a replacement for Dr. Klazien Matter.

Dr. sc. nat. Markus Hasenfratz
Head of Clinical Trial Management

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

	2017	2016
Total patients from Switzerland	1217	1075
Total patients from foreign countries	48	16
Total	**1265**	**1091**

	Patients 2017	Trials 2017	Patients 2016	Trials 2016
Total patients in SAKK trials	885	23	806	24
Total patients in trials of cooperative groups (without IBCSG)	300	23	268	18
Total patients in IBCSG trials	80	3	17	3
Total	**1265**	**49**	**1091**	**45**

Retrospective studies, cohort studies and biobanks	Patients 2017	Patients 2016
EORTC 10085 PRO	2	19
T-Cell Project	9	8
SAKK 63/12	282	324
SAKK 95/16	75	na
Total	**368**	**351**

Further increase in number of trials and patients

In 2017 we saw a pleasing increase in trial activities, with more patients taking part in a greater number of trials. A total of 1265 patients recruited into the 49 open trials run by SAKK represented a substantial increase of 16 %. The Swiss member hospitals contributed 1217 of these patients. The aim of further increasing the number of patients was thus also clearly achieved in 2017. Moreover, ten new SAKK protocols and six new foreign trial protocols were activated in Switzerland.

More submissions in the same processing time

The number of submissions was increased again, while the processing time remained the same. 14 trials, 24 amendments and 42 changes of investigator were submitted and approved. Furthermore, numerous further documents were submitted to the regulatory authorities, for example in order to open additional centers in Switzerland for previously approved trials or to comply with further regulatory requirements. The increase in activities is also reflected in the fact that more and more SAKK trials are also being performed abroad, where they are approved by the local authorities. This is only possible with the support of partner organizations and clinical research organizations (CRO).

Swissmedic inspection confirms the high standard to which SAKK clinical trials are performed

Swissmedic has been performing regular GCP and pharmacovigilance inspections since 2010. In 2017 the Coordinating Center underwent a routine GCP system inspection by Swissmedic for the third time (following inspections in 2011 and 2014). This inspection focused on the following three aspects:

1. Completion of corrective actions implemented following the 2014 inspection.
2. Inspection of the SAKK Safety Office, the internal establishment of which has been in progress since 2015 (formerly outsourced to IBCSG).
3. Validation of our IT systems, with particular emphasis on evaluation of SecuTrial®, the system we use to record, review and manage trial data.

The outcome of the inspection was very gratifying for us and showed us that we are on the right track. All the corrective actions resulting from the 2014 inspection were implemented fully and on schedule.

Dr. phil. Simona Berardi Vilei
Head of Innovation
and Development

Dr. phil. Dirk Klingbiel
Head of Statistics

Innovation and Development

Due to the increased number of activities, the Innovation & Development team is expanding – five new team members started their work in 2017. For the first time in 2017, SAKK was represented at the Swiss Biotech Day. We plan on further developing such activities in order to increase the awarness of SAKK for start-ups and small biotech companies who are developing new treatment options for oncological patients in Switzerland.

Requests for collaborations of large and mid-sized companies and also international CROs are increasing steadily – demonstrating that the efforts of previous years are now showing results. This will help Switzerland to maintain its strong position in research and in the development of clinical trials at early stages. It also offers Swiss patients the opportunity to obtain – at least in the clinical trial setting – new promising molecules and treatments that are not yet available as standard treatment. The collaboration with the ENGOT group is becoming more intense and new trials in early phase or with the use of modified viruses will soon also be available for Swiss patients.

The SAKK 06/14 trial, a collaboration with the Indian company SIIPL and the German VPM, was also successfully activated in Germany, and the Netherlands should join in the beginning of 2018 (see page 44 for details). This trial represents the capacity of SAKK to open and lead trials in the GMO field (genetically modified organism), not only in Switzerland but also abroad. Also, negotiations on the Phase III part are ongoing, which shows the willingness of our partners to establish a long-term collaboration and to cooperate with SAKK until their new product is safe to be registered as a new treatment method.

The first meeting with the previous commission for technology and innovation CTI, now called "Innosuisse", took place this year and the SAKK Board decided that SAKK will become a member of the Health Tech Cluster Switzerland. The platform provides networking possibilities, matchmaking with partners in research and development as well as investors, and gives access to expertise and specialists.

Trial results and publications

Last year, 36 articles involving SAKK appeared in various scientific journals. The full list can be found on page 17. We also wrote a methodical Letter to the Editor ("Absence of Evidence is not Evidence of Absence: The Case of Non-Inferiority" Ann Oncol. 2017 Dec 1;28(12):3100-3101. doi: 10.1093/annonc/mdx498).

Presence at international congresses
SAKK was well represented at the major oncology congresses, including the meeting of the American Society for Clinical Oncology ASCO, the American Society of Hematology ASH, the International Conference on Malignant Lymphoma ICML and the World Conference on Lung Cancer WCLC. We also took part in more local events such as the meetings of the German Society for Hematology and Medical Oncology DGHO and Swiss Urology SGU. A full list of presentations can be found on page 53.

Flurina Hoffmann
Head of Fundraising
and Communications

As part of our statistical advisory work, we were also able to assist with about 20 smaller and larger non-SAKK projects and contribute to presentations and manuscripts. One of the outcomes of this work was an oral presentation at the congress of the European Society for Medical Oncology ESMO given by Dr. med. Laetitia Mauti.

The statistics team produced 11 clinical trial reports, including six final reports for the authorities.

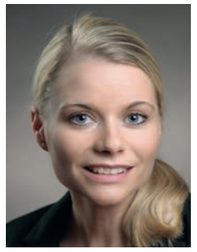
Fundraising and Communications

The increased headcount in fundraising bore fruit in 2017, with income rising by almost 30 per cent. We received approximately CHF 3 million in total from service level agreements and competitive funding. This represents a substantial increase. Our main institutional fundraising partners in 2017 were once again the Swiss Cancer League, the Swiss Cancer Research Foundation, the Swiss Clinical Cancer Research Foundation and the Rising Tide Foundation for Clinical Cancer Research. We received a substantial contribution from the Fond' Action foundation for the first time in 2017. Our sincere thanks go to all these foundations for their generous contributions, which enable us to pursue important research projects that are not funded by the pharmaceutical industry.

We would also like to thank the foundations that have supported us repeatedly with smaller amounts: the Basel Cancer League, the Ernst Göhner Foundation, the Cancer League of Central Switzerland, and the Foundation to Promote Medical and Biological Research as well as other organizations. And naturally we would like to express our thanks to our industry partners who, as members of the industry pool, make a major contribution to enabling us to repeatedly offer attractive further training courses of innovative scientific value.

The events we held for specialists and our public events were very popular. The second Young Oncology Academy deserves a special mention. More information about this on page 14 and 16.

Hans-Peter Röthlisberger
Head of Services



Stéphanie Mohler
Head of Human Resources

Finances

The negative interest on liquid assets was a major challenge in the past financial year. We worked with our banks to find solutions that enabled us to avoid paying negative interest as far as possible.

House of Clinical Research
In 2017, further organizations decided to rent offices in the building at Effingerstrasse 33: the Swiss Clinical Trial Organization SCTO, the Swiss Clinical Cancer Research Foundation, the Swiss Pednet, the European Patients' Academy EUPATI, and Swiss Cancer Screening. We are delighted to be able to intensify our collaboration with these organizations and to make use of the synergies offered by their proximity.

IT
A major investment was made last year in safeguarding against the failure of our IT infrastructure. Virtualization was consolidated on state-of-the-art software (Microsoft Hyper-V). Our e-mail server was set up redundantly, back-up provision was increased, system monitoring was expanded and further investment was made in security (firewall, virus protection, content filtering).

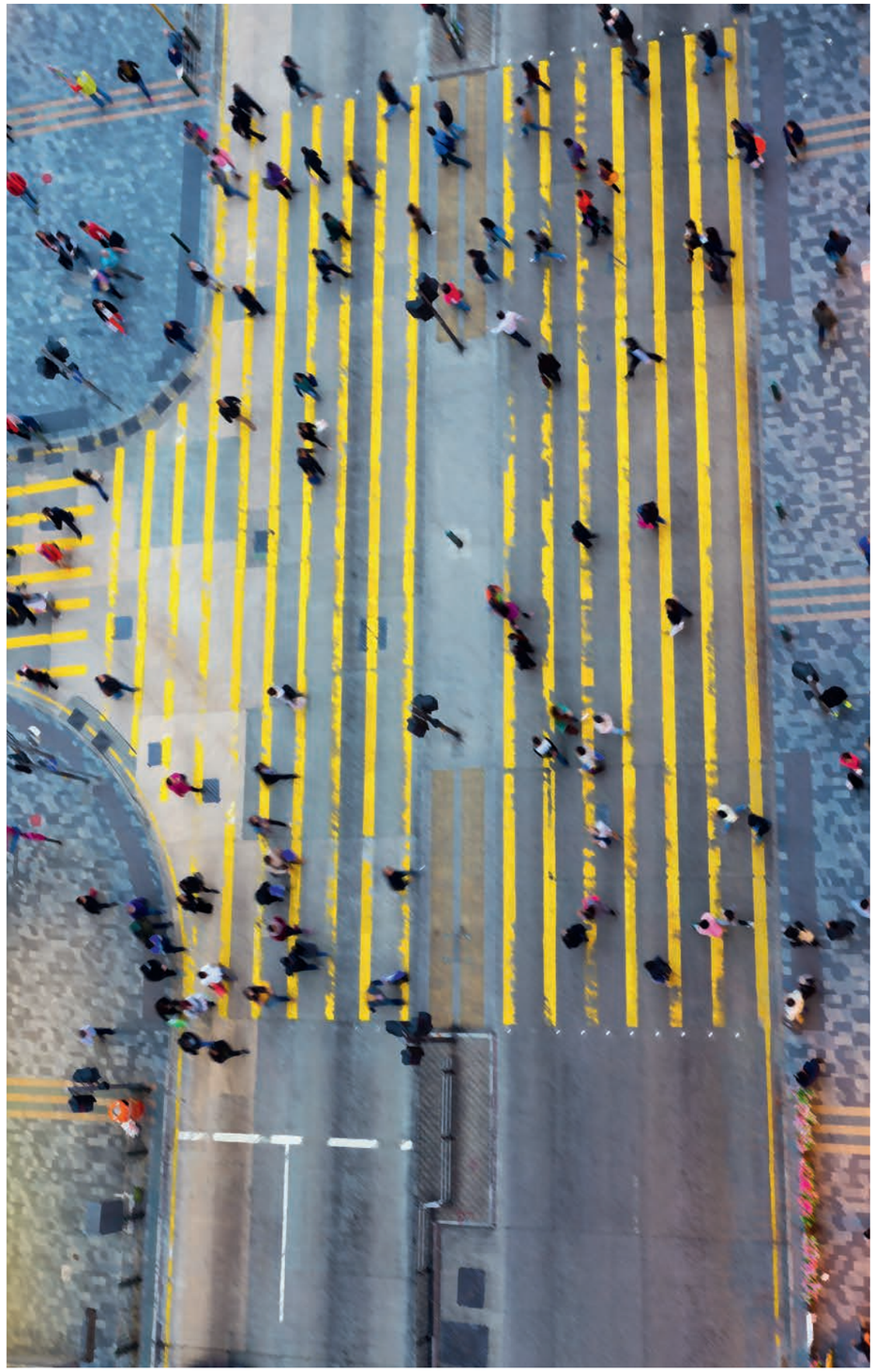
Human resources

The number of employees at SAKK has increased from 24 in 2005 to 80 today. Five additional members of staff were recruited in various departments in 2017 alone. Growth means change, and the associated changes to processes and responsibilities can lead to uncertainty among employees. The successful integration of new human resources is determined fundamentally by the quality of the management.

It was against this background that the SAKK management decided in 2017 to make even better use of the potential of its managers (departmental heads and team leaders) by instigating a supervised, professional management process. Continuous performance-related planning and review processes take place within this process with the aim of reliably developing key individuals with the necessary competencies.

Regular workshops are held to discuss and develop management-related topics such as organizational structure, communication, conflict management, evaluation, corporate culture and more. This coaching is a medium-term project designed to ensure the capacity to act and effectiveness of both the individual and the organization in a constantly changing environment – and the ability, to achieve outstanding performance by working together.

2017	1. January	31. December
Full-time employees (FT)	61.3	65.9
Employee headcount (HC)	73.0	80.0



Balance sheet

As of December 31 (in CHF)	**2017**		**2016**	
Assets				
Cash and cash equivalents	10’722’782.87		9’614’150.38	
Accounts receivable	3’032’967.90		2’496’911.42	
Other accounts receivable	19’402.27		36’433.82	
Prepaid expenses and deferred income	1’209’488.62		914’076.13	
Total current assets	**14’984’641.66**	61.0 %	**13’061’571.75**	59.6 %
Financial assets	9’574’772.00		8’854’960.00	
Total fixed assets	**9’574’772.00**	39.0 %	**8’854’960.00**	40.4 %
Total assets	**24’559’413.66**	100.0 %	**21’916’531.75**	100.0 %
Liabilities				
Accounts payable	2’221’002.05		2’506’231.14	
Other accounts payable	120’335.10		80’372.35	
Deferred income and accrued expenses	7’157’310.17		5’595’303.00	
Total short-term liabilities	**9’498’647.32**	38.7 %	**8’181’906.49**	37.3 %
Provisions for liability claims	608’155.88		608’155.88	
Other Provisions	-		90’000.00	
Total long-term liabilities	608’155.88	2.5 %	698’155.88	3.2 %
«Education Grant» fund	30’000.00		30’000.00	
«Special purpose» fund	67’932.38		17’932.38	
«Hubacher» fund	10’389’996.94		9’708’589.74	
Total special purpose fund capital	10’487’929.32	42.7 %	9’756’522.12	44.5 %
Organizational capital				
Free capital as at 1 January	3’279’947.26		2’479’798.22	
Group result	684’733.88		800’149.04	
Free capital as at 31 December	3’964’681.14		3’279’947.26	
Total organizational capital	3’964’681.14	16.1%	3’279’947.26	15.0 %
Total liabilities	**24’559’413.66**	100.0 %	**21’916’531.75**	100.0 %

Statement of operations

January 1 to December 31 (in CHF)	**2017**		**2016**	
Operating income				
Research contributions SERI[1]	5’832’434.00		5’885’400.00	
Research contributions CLS[2]	493’000.00		352’650.00	
Research contributions CRS[3]	1’428’800.00		1’152’800.00	
Research contributions SSKK[4]	250’000.00		50’000.00	
Research contributions, third parties	864’774.90		723’344.81	
Research contributions, Swiss health insurers	1’482’271.60		1’711’295.50	
Income from industry partnerships	4’272’981.86		3’830’843.23	
Income from foreign study groups	1’558’401.62		66’348.30	
Income from Cancer Bulletin	275’685.00		298’284.63	
Income from Patient Advisory Board	35’275.00		-	
Donations, bequests, legacies	519’083.68		1’860’977.79	
Miscellaneous income	958’995.52		517’212.04	
Losses on receivables	-104’000.00		-372’000.00	
Total operating income	**17’867’703.18**	100.0 %	**16’077’156.30**	100.0 %
Operating costs				
Miscellaneous study-related expenses	-1’418’703.09		-1’337’110.18	
Research contributions IBCSG[5], ETOP	-293’333.00		-163’333.00	
Research contributions, centers	-4’953’549.57		-4’084’423.33	
Travel, hospitality expenses	-567’112.77		-414’797.86	
Other operating expenses	-184’406.29		-147’033.35	
Total operating expenses	**-7’417’104.72**	-41.5 %	**-6’146’697.72**	-38.2 %
Interim result 1	**10’450’598.46**	58.5 %	**9’930’458.58**	61.8 %
Coordination expenses				
Personnel expenses	-8’279’637.82		-7’794’781.88	
Other coordination expenses	-1’537’896.89		-1’313’788.07	
Total coordination expenses	**-9’817’534.71**	-54.9 %	**-9’108’569.95**	-56.7 %
Interim result 2	**633’063.75**	3.5 %	**821’888.63**	5.1%
Financial result				
Financial income	75’301.58		4’577.50	
Financial expenses	-23’631.45		-26’040.45	
Total financial result	**51’670.13**	0.3 %	**-21’462.95**	-0.1 %
Interim result 3	**684’733.88**	3.8 %	**800’425.68**	5.0 %
Out-of-period result				
Out-of period income	-		-	
Out-of period expenses	-		-276.64	
Total out-of-period result relating to a different accounting period	-	0.0 %	-276.64	0.0 %
Annual result	**684’733.88**	3.8 %	**800’149.04**	5.0 %

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 2017 annual financial statements

As of December 31	2017	2016
Information compliant with Art. 957–962 SCO		
Number of personnel		
Bandwidth of full-time equivalents (average for year)	>50–250	>50–250
Valuation of assets at market value		
Financial investments at market value on 31.12	9'574'772.00 CHF	8'854'960.00 CHF
Auditors' fee		
Fee for auditing services	13'600.00 CHF	7'500.00 CHF
Fee for other services	0.00 CHF	0.00 CHF

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

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BERICHT DER REVISIONSSTELLE

An die Mitgliederversammlung der Schweizerischen Arbeitsgemeinschaft für klinische Krebsforschung SAKK, Bern.

Bericht der Revisionsstelle zur Jahresrechnung

Als Revisionsstelle haben wir die beiliegende Jahresrechnung der Schweizerischen Arbeitsgemeinschaft für klinische Krebsforschung SAKK bestehend aus Bilanz, Betriebsrechnung, Geldflussrechnung, Rechnung über die Veränderung des Kapitals, Rechnung über die Veränderung der Fonds und Anhang für das am 31. Dezember 2017 abgeschlossene Geschäftsjahr geprüft.

Verantwortung des Vorstandes

Der Vorstand ist für die Aufstellung der Jahresrechnung in Übereinstimmung mit den gesetzlichen Vorschriften und den Statuten verantwortlich. Diese Verantwortung beinhaltet die Ausgestaltung, Implementierung und Aufrechterhaltung eines internen Kontrollsystems mit Bezug auf die Aufstellung einer Jahresrechnung, die frei von wesentlichen falschen Angaben als Folge von Verstössen oder Irrtümern ist. Darüber hinaus ist der Vorstand für die Auswahl und die Anwendung sachgemässer Rechnungslegungsmethoden sowie die Vornahme angemessener Schätzungen verantwortlich.

Verantwortung der Revisionsstelle

Unsere Verantwortung ist es, aufgrund unserer Prüfung ein Prüfungsurteil über die Jahresrechnung abzugeben. Wir haben unsere Prüfung in Übereinstimmung mit dem schweizerischen Gesetz und den Schweizer Prüfungsstandards vorgenommen. Nach diesen Standards haben wir die Prüfung so zu planen und durchzuführen, dass wir hinreichende Sicherheit gewinnen, ob die Jahresrechnung frei von wesentlichen falschen Angaben ist.

Eine Prüfung beinhaltet die Durchführung von Prüfungshandlungen zur Erlangung von Prüfungsnachweisen für die in der Jahresrechnung enthaltenen Wertansätze und sonstigen Angaben. Die Auswahl der Prüfungshandlungen liegt im pflichtgemässen Ermessen des Prüfers. Dies schliesst eine Beurteilung der Risiken wesentlicher falscher Angaben in der Jahresrechnung als Folge von Verstössen oder Irrtümern ein. Bei der Beurteilung dieser Risiken berücksichtigt der Prüfer das interne Kontrollsystem, soweit es für die Aufstellung der Jahresrechnung von Bedeutung ist, um die den Umständen entsprechenden Prüfungshandlungen festzulegen, nicht aber um ein Prüfungsurteil über die Wirksamkeit des internen Kontrollsystems abzugeben. Die Prüfung umfasst zudem die Beurteilung der Angemessenheit der angewandten Rechnungslegungsmethoden, der Plausibilität der vorgenommenen Schätzungen sowie eine Würdigung der Gesamtdarstellung der Jahresrechnung. Wir sind der Auffassung, dass die von uns erlangten Prüfungsnachweise eine ausreichende und angemessene Grundlage für unser Prüfungsurteil bilden.

Prüfungsurteil

Nach unserer Beurteilung entspricht die Jahresrechnung für das am 31. Dezember 2017 abgeschlossene Geschäftsjahr dem schweizerischen Gesetz und den Statuten.

Berichterstattung aufgrund weiterer gesetzlicher Vorschriften

Wir bestätigen, dass wir die gesetzlichen Anforderungen an die Zulassung gemäss Revisionsaufsichtsgesetz (RAG) und die Unabhängigkeit (Art. 728 OR) erfüllen und keine mit unserer Unabhängigkeit nicht vereinbaren Sachverhalte vorliegen.

In Übereinstimmung mit Art. 728a Abs. 1 Ziff. 3 OR und dem Schweizer Prüfungsstandard 890 bestätigen wir, dass ein gemäss den Vorgaben des Vorstandes ausgestaltetes internes Kontrollsystem für die Aufstellung der Jahresrechnung existiert.

Bern, 26. März 2018

BDO AG

Matthias Hildebrandt
Zugelassener Revisionsexperte

Simon Kehrli
Leitender Revisor
Zugelassener Revisionsexperte

Advisory Board

General Assembly

Aargau	Baden	Basel	Bern	Biel
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Gastrointestinal Cancer
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Leukemia
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Lung Cancer
PD Dr. med. Martin Früh

Lymphoma
PD Dr. med. Urban Novak

New Anticancer Treatments
PD Dr. med. Markus Jörger

Urogenital Tumors
PD Dr. med. Richard Cathomas

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PD Dr. med. Sheila Unger

Network for Outcomes Research
Dr. med. Konstantin Dedes

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Radio-Oncology
Prof. Dr. med. Frank Zimmermann

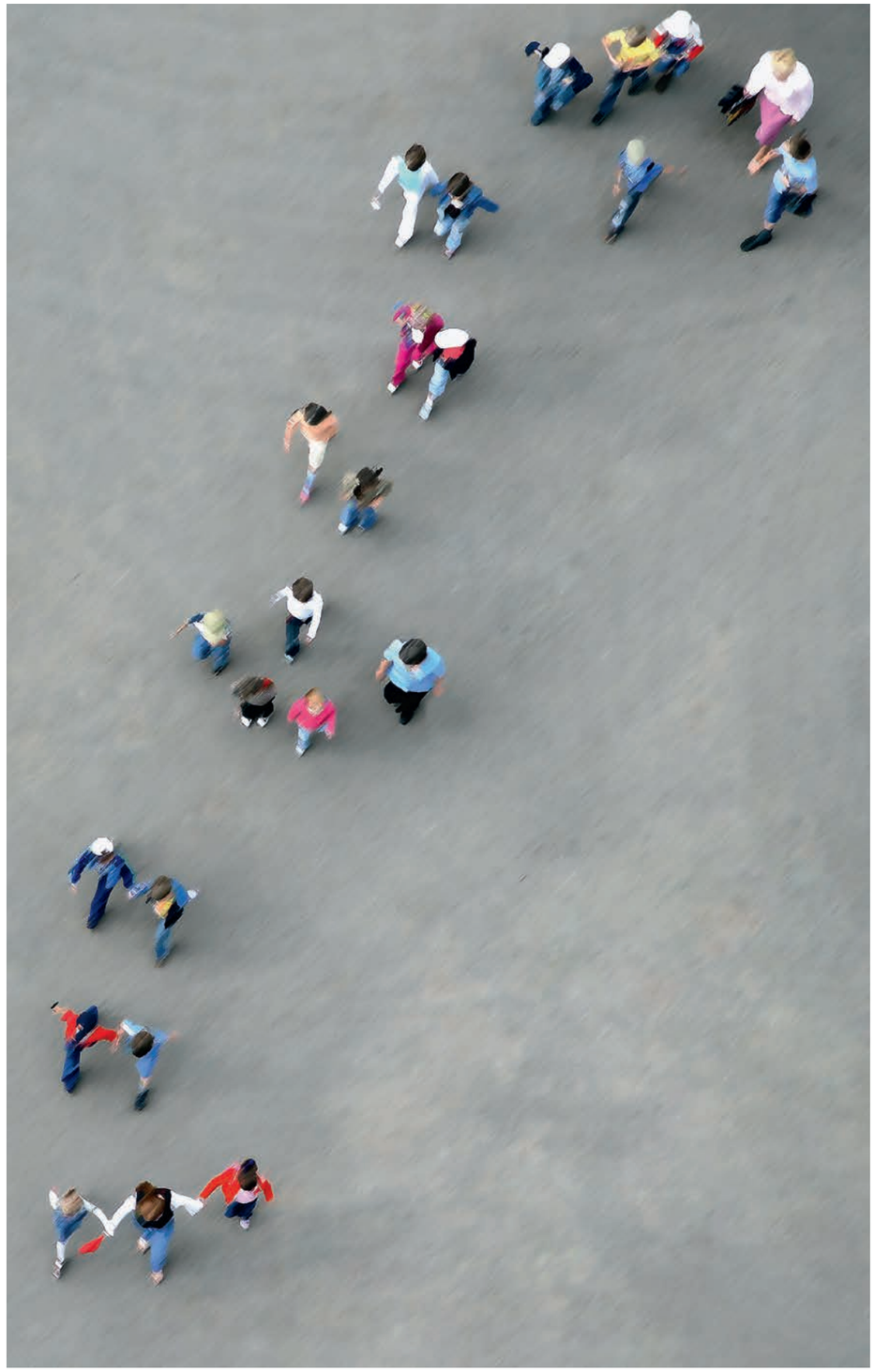
Surgery
Prof. Dr. med. Christoph Kettelhack

SAKK Coordinating Center

CEO

Executive Board

- Clinical Trial Management
- Innovation & Development
- Statistics
- Quality Assurance & Regulatory Affairs
- Fundraising & Communications
- Services



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Oncology Institute of Southern
Switzerland (IOSI) Bellinzona

The Swiss Group for Clinical Cancer Research SAKK expresses its gratitude!
In 2017 we were again able to conduct trials in over 50 centers in Switzerland and at various hospitals in other countries. A total of 1265 patients were enrolled in clinical trials and in this way were given access to new treatment representing the best possible option according to present scientific knowledge. This was only possible thanks to the generous support of our partner organizations, corporate partners, donors and institutional sponsors. We would also like to extend our sincere thanks to those who made a bequest to the Swiss Group for Clinical Cancer Research.

SAKK Industry Pool 2017
Sincere thanks go to the supporting pharmaceutical companies:

- AbbVie AG
- Amgen Switzerland AG
- Astellas Pharma AG
- AstraZeneca AG
- Bayer (Schweiz) AG
- Boehringer Ingelheim (Schweiz) GmbH
- Bristol-Myers Squibb SA
- Celgene GmbH
- Eli Lilly (Suisse) SA
- Genomic Health Intl' Sàrl
- Gilead Sciences Switzerland Sàrl
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- Sanofi-Aventis (Schweiz) AG
- Shire
- Takeda Pharma AG
- TESARO Bio GmbH
- Teva Pharma AG
- Vifor AG

Contributions from the public sector and third parties:
- State Secretariat for Education, Research and Innovation (SERI)
- Swiss Cancer Research Foundation
- Swiss Cancer League

- Bernese Cancer League
- Bequests
- Cancer League of Central Switzerland
- Cancer League Basel
- Foundation for the fight against cancer
- Gateway for Cancer Research
- Private donors
- Promedica
- Rising Tide Foundation for Clinical Cancer Research
- Swiss Clinical Cancer Research Foundation
- Werner & Hedy Berger-Janser Foundation

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PC 60-295422-0

Conducted trials 2017

Trials activated in 2017

Trial name	Trial title	Coordinating Investigator	Activated
Gastrointestinal Cancers			
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
PRODIGE 32	Systematic surgery vs. monitoring and salvage surgery in operable oesophageal cancer in complete clinical response after chemotherapy. Strategic multicenter randomized phase II-III trial.	Thomas Ruhstaller	28.03.2017
Leukemias			
CLL13	A phase 3 multicenter, randomized, prospective, open-label trial of standard chemoimmunotherapy (FCR/BR) versus rituximab plus venetoclax (RVe) versus obinutuzumab (GA101) plus venetoclax (GVe) versus obinutuzumab plus ibrutinib plus venetoclax (GIVe) in fit patients with previously untreated chronic lymphocytic leukemia (CLL) without Del(17p) or TP53 mutation.	Michael Gregor	17.07.2017
HOVON 103 - SEL	A randomized phase II multicenter study with a safety run-in to assess the tolerability and efficacy of the addition of oral selinexor (KPT-330) to standard induction chemotherapy in AML and high risk myelodysplasia (MDS) (IPSS-R > 4.5) in patients aged ≥ 66 years.	Georg Stüssi	19.06.2017
Lung Cancers			
ETOP BOOSTER	A randomised phase II trial of osimertinib and bevacizumab versus osimertinib alone as second-line treatment in stage IIIb-IVb NSCLC with confirmed EGFRm and T790M.	Martin Früh	15.06.2017
ETOP PROMISE-meso	A multicentre randomised phase III trial comparing pembrolizumab versus standard chemotherapy for advanced pre-treated malignant pleural mesothelioma.	Alessandra Curioni	06.09.2017
SAKK 17/16	Lurbinectedin Monotherapy in Patients with Progressive Malignant Pleural Mesothelioma. A Multicenter, Single-arm Phase II Trial.	Ioannis Metaxas	28.09.2017
SAKK 19/16	Binimetinib, pemetrexed and cisplatin, followed by maintenance with binimetinib and pemetrexed, in patients with advanced non-small cell lung cancer with KRAS mutations. A multicenter phase IB trial.	Martin Früh	25.04.2017
Lymphomas			
SAKK 35/15	A phase I trial of obinutuzumab in combination with venetoclax in previously untreated follicular lymphoma patients.	Anastasios Stathis	23.02.2017
HD 21	HD21 for advanced stages: Treatment optimization trial in the first-line treatment of advanced stage Hodgkin lymphoma; comparison of 4-6 cycles of escalated BEACOPP with 4-6 cycles of BrECADD.	Alden Moccia	29.03.2017
Urogenital Cancers			
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 08/15	Multicenter, Randomized Phase II Trial of Salvage Radiotherapy +/- Metformin for Patients with Prostate Cancer after Prostatectomy.	Alan Dal Pra	22.09.2017
SAKK 08/16	ODM-201 maintenance therapy in patients with metastatic castration resistant prostate cancer (mCRPC) previously treated with one novel hormonal agent first line and non-progressive disease after second line treatment with a taxane: A multicenter randomized double-blind placebo-controlled phase II trial.	Silke Gillessen	31.03.2017
Head and Neck Cancers			
SAKK 10/16	Phase III study assessing The "best of" radiotherapy compared to the "best of" surgery (trans-oral surgery (TOS) in patients with T1-T2, N0 oropharyngeal carcinoma.	Frank Zimmermann	27.11.2017
New Anticancer Treatments			
EORTC-1420-HNCG-ROG 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
Supportive and Palliative Cancer Care			
SAKK 95/16	Patterns of care for patients with metastatic bone disease in solid tumors – a cross sectional survey study.	Michael Mark	01.11.2017

Trials open for accrual in 2017

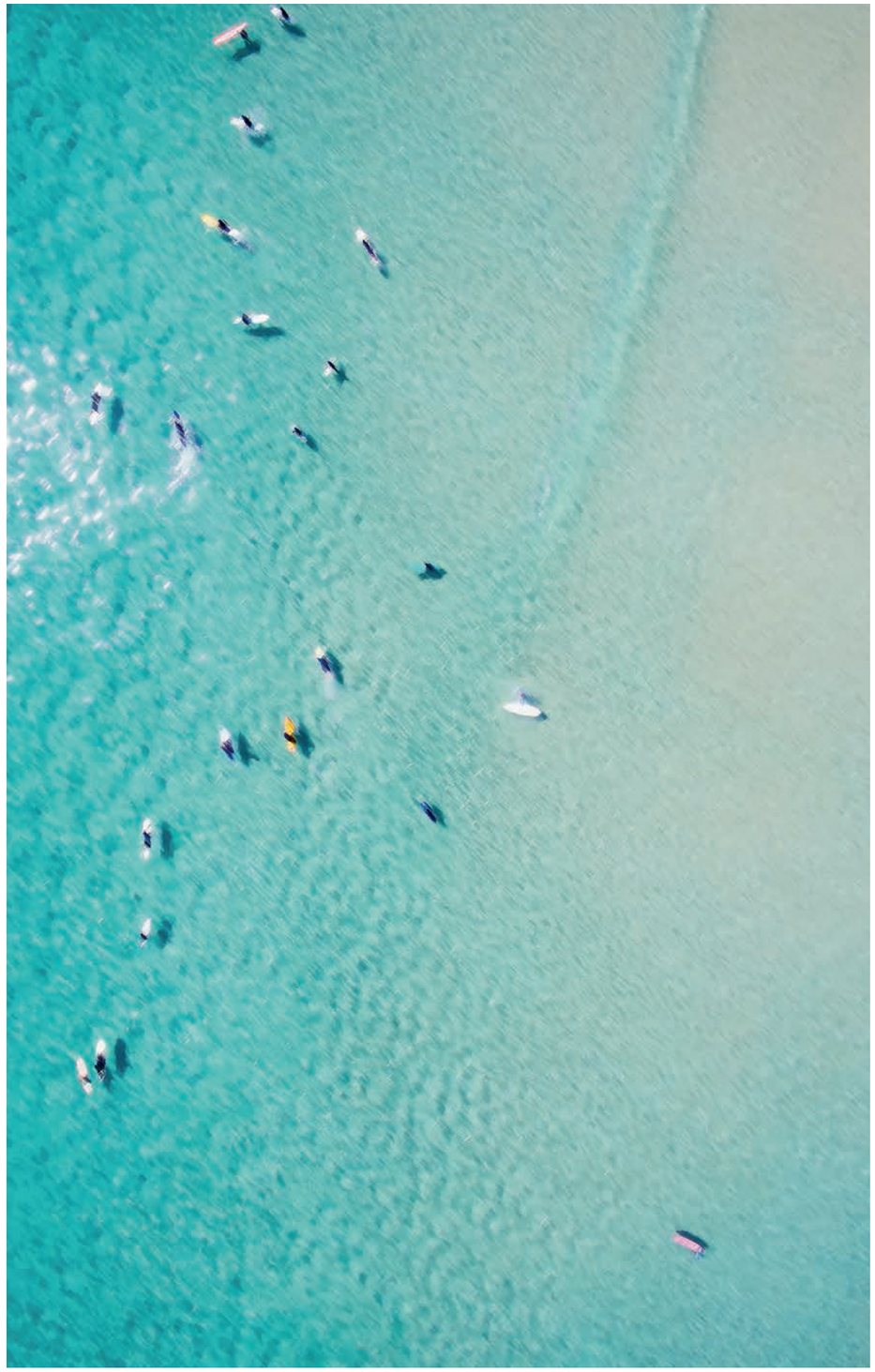
Trial name	Trial title	Coordinating Investigator	Activated
Breast Cancers			
SAKK 21/12	A stratified, multicenter Phase II trial of transdermal CR1447 (4-OH-testosterone) in endocrine responsive-HER2 negative and triple negative-androgen receptor positive metastatic or locally advanced breast cancer.	Marcus Vetter	14.04.2014
SAKK 24/14	Anti-EGFR-immunoliposomes loaded with doxorubicin in patients with advanced triple negative EGFR positive breast cancer – A multicenter single arm phase II trial.	Ralph Winterhalder	20.10.2016
SAKK 25/14	Eribulin as 1st line treatment in elderly patients (≥ 70 years) with advanced breast cancer: a multicenter phase II trial.	Ursula Hasler-Strub	11.08.2015
SAKK 28/12	Standardization project for Ki-67 assessment in G2 breast cancer. A retrospective study (samples only).	Zsuzsanna Varga	02.03.2016
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
EORTC 10085 PRO	EORTC 10085 prospective part, Clinical and biological characterization of Male Breast Cancer: an international EORTC, BIG and NABCG intergroup study.	Stefan Aebi	02.07.2014
IBCSG 48-14 POSITIVE	A study evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy (POSITIVE).	Olivia Pagani	02.12.2014
IBCSG 50-14 OLYMPIA	A randomised, double-blind, parallel group, placebo-controlled multi-centre Phase III study to assess the efficacy and safety of olaparib vs placebo as adjuvant treatment in patients with high risk germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy.	Urban Novak	23.11.2015

Trial name	Trial title	Coordinating Investigator	Activated
IBCSG 52-15 PALLAS	PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of Palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)-negative early breast cancer.	Marcus Vetter	08.11.2016
Gastrointestinal Cancers			
SAKK 41/13	Adjuvant aspirin treatment in PIK3CA mutated colon cancer patients. A randomized, double-blinded, placebo-controlled, phase III trial.	Ulrich Güller	26.04.2016
SAKK 41/14	Physical activity program in patients with metastatic colorectal cancer who receive palliative first-line chemotherapy. A multicenter open label randomized controlled phase III trial.	Viviane Hess	29.01.2016
SAKK 41/16	SAKK 41/16 (RECAP trial): Neoadjuvant treatment with Regorafenib and Capecitabine combined with radiotherapy in locally advanced rectal cancer. A Phase Ib trial.	Sara Bastian	27.02.2017
PRODIGE 32	Systematic surgery vs. monitoring and salvage surgery in operable oesophageal cancer in complete clinical response after chemotherapy. Strategic multicenter randomized phase II-III trial.	Thomas Ruhstaller	28.03.2017
PROSPECT	A phase II/III trial of neoadjuvant folfox, with selective use of combined modality chemoradiation vs. preoperative combined modality chemoradiation for locally advanced rectal cancer patients undergoing low anterior resection with total mesorectal excision.	Michael Montemurro	02.07.2015
Gynecological Cancers			
INOVATYON	Phase III international, randomized study of trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum.	Cristiana Sessa	28.03.2014
Head and Neck Cancers			
SAKK 10/16	Phase III study assessing The "best of" radiotherapy compared to the "best of" surgery (trans-oral surgery (TOS) in patients with T1-T2, N0 oropharyngeal carcinoma.	Frank Zimmermann	27.11.2017
Leukemias			
CLL13	A phase 3 multicenter, randomized, prospective, open-label trial of standard chemoimmunotherapy (FCR/BR) versus rituximab plus venetoclax (RVe) versus obinutuzumab (GA101) plus venetoclax (GVe) versus obinutuzumab plus ibrutinib plus venetoclax (GIVe) in fit patients with previously untreated chronic lymphocytic leukemia (CLL) without Del(17p) or TP53 mutation.	Michael Gregor	17.07.2017
CML-V	Treatment optimization of newly diagnosed Ph/BCR-ABL positive patients with chronic myeloid leukemia (CML) in chronic phase with nilotinib vs. nilotinib plus interferon alpha induction and nilotinib or interferon alpha maintenance therapy.	Gabriela Baerlocher	14.02.2014
EBMT HCT vs CT	Compare conventional chemotherapy to low dose total body irradiation-based conditioning and hematopoietic cell transplantation as consolidation therapy.	Yves Chalandon	12.07.2011
GRAALL 2014	Treatment of adult acute lymphoblastic leukemia (ALL), evaluating the addition of a second late intensification course in B-lineage PH-negative ALL, the addition of Nelarabine in high-risk T-lineage ALL, and the reduction of chemotherapy intensity in Ph+ ALL.	Yves Chalandon	03.05.2016
HOVON 103 - SEL	A randomized phase II multicenter study with a safety run-in to assess the tolerability and efficacy of the addition of oral selinexor (KPT-330) to standard induction chemotherapy in AML and high risk myelodysplasia (MDS) (IPSS-R > 4.5) in patients aged ≥ 66 years.	Georg Stüssi	19.06.2017
HOVON 132	Randomized study with a run-in dose-selection phase to assess the added value of lenalidomide in combination with standard remission-induction chemotherapy and post-remission treatment in patients aged 18-65 years with previously untreated acute myeloid leukemia (AML) or high risk myelodysplasia (MDS) (IPSS-R risk score > 4.5).	Thomas Pabst	04.05.2015
HOVON 135	A randomized phase II multicenter study to assess the tolerability and efficacy of the addition of ibrutinib to 10-day decitabine in UNFIT (i.e. HCT-CI ≥ 3) AML and high risk myelodysplasia (MDS) (IPSS-R > 4.5) patients aged ≥ 66 years. A study in the frame of the master-protocol of parallel randomized phase II studies in UNFIT-older AML/high-risk MDS patients.	Sabine Blum	26.10.2016
Lung Cancers			
SAKK 15/12	Early prophylactic cranial irradiation with hippocampal avoidance in patients with limited disease small-cell lung cancer. A multicenter phase II trial.	Hansjörg Vees	11.07.2014
SAKK 16/14	Anti-PD-L1 antibody MEDI4736 in addition to neoadjuvant chemotherapy in patients with stage IIIA (N2) non-small cell lung cancer (NSCLC). A multicenter single-arm phase II trial.	Sacha Rothschild	11.04.2016
SAKK 17/16	Lurbinectedin Monotherapy in Patients with Progressive Malignant Pleural Mesothelioma. A Multicenter, Single-arm Phase II Trial.	Ioannis Metaxas	28.09.2017
SAKK 19/16	Binimetinib, pemetrexed and cisplatin, followed by maintenance with binimetinib and pemetrexed, in patients with advanced non-small cell lung cancer with KRAS mutations. A multicenter phase IB trial.	Martin Früh	25.04.2017
EORTC PEARLS	A randomized, phase 3 trial with anti-PD-1 monoclonal antibody pembrolizumab (MK-3475) versus placebo for patients with early stage NSCLC after resection and completion of standard adjuvant therapy (PEARLS).	Alessandra Curioni Fontecedro	08.02.2016
ETOP BOOSTER	A randomised phase II trial of osimertinib and bevacizumab versus osimertinib alone as second-line treatment in stage IIIb-IVb NSCLC with confirmed EGFRm and T790M.	Martin Früh	15.06.2017
ETOP PROMISE-meso	A multicentre randomised phase III trial comparing pembrolizumab versus standard chemotherapy for advanced pre-treated malignant pleural mesothelioma.	Alessandra Curioni	06.09.2017

Trial name	Trial title	Coordinating Investigator	Activated
ETOP SPLEN-DOUR	A randomised, open-label phase III trial evaluating the addition of denosumab to standard first-line anticancer treatment in advanced NSCLC.	Roger von Moos	12.01.2015
Lung ART EO-RTC	LungArt: Phase III study comparing post-operative conformal radiotherapy to no post-operative radiotherapy in patients with completely resected non-small cell lung cancer and mediastinal N2 Involvement.	Riesterer Oliver	18.05.2015
Lymphomas			
SAKK 35/14	Rituximab with or without ibrutinib for untreated patients with advanced follicular lymphoma in need of therapy. A randomized, double-blinded, SAKK and NLG collaborative Phase II trial.	Emanuele Zucca	15.10.2015
SAKK 35/15	A phase I trial of obinutuzumab in combination with venetoclax in previously untreated follicular lymphoma patients.	Anastasios Stathis	23.02.2017
SAKK 36/13	Combination of ibrutinib and Bortezomib followed by ibrutinib maintenance to treat patients with relapsed and refractory mantle cell lymphoma. A multicenter Phase I/II trial.	Urban Novak	11.08.2015
HD 17	Treatment optimization trial in the first-line treatment of intermediate stage Hodgkin lymphoma; treatment stratification by means of FDG-PET.	Andreas Lohri	13.02.2013
HD 21	HD21 for advanced stages: Treatment optimization trial in the first-line treatment of advanced stage Hodgkin lymphoma; comparison of 4-6 cycles of escalated BEACOPP with 4-6 cycles of BrECADD.	Alden Moccia	29.03.2017
IELSG-37	A randomized, open-label, multicentre, two-arm phase III comparative study assessing the role of involved mediastinal radiotherapy after Rituximab containing chemotherapy regimens to patients with newly diagnosed Primary Mediastinal Large B-Cell Lymphoma (PMLBCL).	Emanuele Zucca	15.11.2011
Urogenital Cancers			
SAKK 01/10	Carboplatin Chemotherapy and Involved Node Radiotherapy in Stage IIA/B Seminoma.	Alexandros Papachristofilou	15.06.2012
SAKK 06/14	A phase I/II open label clinical trial assessing safety and efficacy of intravesical instillation of VPM1002BC in patients with recurrent non-muscle invasive bladder cancer after standard BCG therapy.	Cyrill Rentsch	07.09.2015
SAKK 07/17	Nivolumab in combination with Ipilimumab in patients with metastatic renal cell carcinoma: A multicenter single-arm phase II trial.	Frank Stenner	13.12.2017
SAKK 08/14	Investigation of Metformin in patients with castration resistant Prostate Cancer in combination with Enzalutamide vs. Enzalutamide alone (IMPROVE TRIAL). A randomized, open label, phase II trial.	Christian Rothermundt	20.05.2016
SAKK 08/15	Multicenter, Randomized Phase II Trial of Salvage Radiotherapy +/- Metformin for Patients with Prostate Cancer after Prostatectomy.	Alan Dal Pra	22.09.2017
SAKK 08/16	ODM-201 maintenance therapy in patients with metastatic castration resistant prostate cancer (mCRPC) previously treated with one novel hormonal agent first line and non-progressive disease after second line treatment with a taxane: A multicenter randomized double-blind placebo-controlled phase II trial.	Silke Gillessen	31.03.2017
SAKK 63/12	Prospective cohort study with collection of clinical data, serum and plasma of patients with prostate disease.	Daniel Engeler	15.10.2014
SAKK 96/12	Prevention of Symptomatic Skeletal Events with Denosumab Administered every 4 Weeks versus every 12 Weeks – A Non-Inferiority Phase III Trial.	Roger Von Moos	16.07.2014
STAMPEDE	Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy A multi-arm multi-stage randomised controlled trial.	George Thalmann	11.01.2010
New Anticancer Treatments			
SAKK 11/16	Personalized and cell-based antitumor immunization MVX-ONCO-1 in advanced head and neck squamous cell carcinoma. A single arm, open label, multicenter phase II trial.	Olivier Michielin	27.06.2017
SAKK 67/15	An open-label Phase 1/2a study of BAL101553 administered as intravenous 48-hour infusions in adult patients with advanced solid tumors.	Markus Joerger	19.08.2016
Supportive and Palliative Cancer Care			
SAKK 95/16	Patterns of care for patients with metastatic bone disease in solid tumors – a cross sectional survey study.	Michael Mark	01.11.2017

Trials closed for accrual in 2017

Trial name	Trial title	Coordinating Investigator	Activated	Closed
Breast Cancers				
SAKK 28/12	Standardization project for Ki-67 assessment in G2 breast cancer. A retrospective study (samples only).	Zsuzsanna Varga	02.03.2016	31.01.2017
EORTC 10085 PRO	EORTC 10085 prospective part, Clinical and biological characterization of Male Breast Cancer: an international EORTC, BIG and NABCG intergroup study.	Stefan Aebi	02.07.2014	28.02.2017
Gynecological Cancers				
INOVATYON	Phase III international, randomized study of trabectedin plus Pegylated Liposomal Doxo-rubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum.	Cristiana Sessa	28.03.2014	18.09.2017
Leukemias				
CML-V	Treatment optimization of newly diagnosed Ph/BCR-ABL positive patients with chronic myeloid leukemia (CML) in chronic phase with nilotinib vs. nilotinib plus interferon alpha induction and nilotinib or interferon alpha maintenance therapy.	Gabriela Baerlocher	14.02.2014	31.07.2017
EBMT HCT vs CT	Compare conventional chemotherapy to low dose total body irradiation-based conditioning and hematopoietic cell transplantation as consolidation therapy.	Yves Chalandon	12.07.2011	01.08.2017
HOVON 132	Randomized study with a run-in dose-selection phase to assess the added value of lenalido-mide in combination with standard remis-sion-induction chemotherapy and post-remis-sion treatment in patients aged 18-65 years with previously untreated acute myeloid leu-kemia (AML) or high risk myelodysplasia (MDS) (IPSS-R risk score > 4.5).	Thomas Pabst	04.05.2015	09.08.2017
Lung Cancers				
SAKK 15/12	Early prophylactic cranial irradiation with hip-pocampal avoidance in patients with limited disease small-cell lung cancer. A multicenter phase II trial.	Hansjörg Vees	11.07.2014	09.08.2017
Lymphomas				
HD 17	Treatment optimization trial in the first-line treatment of intermediate stage Hodgkin lymphoma; treatment stratification by means of FDG-PET.	Andreas Lohri	13.02.2013	21.03.2018



Accrual numbers per disease and member

Urogenital Cancers	Lung Cancers	Breast Cancers	Leukemias	Lymphomas	Gastrointestinal Cancers	Gynaecological cancers	Supportive and Palliative Cancer Care	New Anticancer Treatments*	**Total**		
472	**127**	**253**	**150**	**93**	**72**	**10**	**75**	**13**	**1265**	Members	Hospitals
6	2	6	13	5	4	0	0	0	**36**	**Aargau**	**Kantonsspital Aarau**
17	2	5	0	0	4	0	0	0	**28**	**Baden**	**Kantonsspital Baden**
47	8	27	20	6	8	1	7	0	**124**	**Basel**	**Universitätsspital Basel Claraspital Kantonsspital Baselland Liestal Brustzentrum Basel – Praxis Thorn Onkopraxis Dr. med. A. Dieterle**
58	10	13	22	9	0	1	0	0	**113**	**Bern**	**Inselspital Lindenhofgruppe - Engeriedspital**
0	0	0	0	0	0	0	0	0	**0**	**Biel**	**Spitalzentrum AG**
55	6	5	3	2	4	0	0	0	**75**	**Fribourg**	**Hôpital Fribourgeois Hôpital Neuchâtelois**
55	6	13	11	2	1	0	0	0	**88**	**Genève**	**Hôpitaux Universitaires de Genève**
48	20	15	1	7	4	0	31	3	**129**	**Graubünden**	**Kantonsspital Graubünden**
3	1	21	0	0	4	0	22	0	**51**	**Hirslanden**	**Hirslanden Klinik Hirslanden Hirslanden Klinik Im Park Hirslandenklinik Aarau Hirslandenklinik Andreasklinik Hirslandenklinik St. Anna Brustzentrum (Seefeld)**
8	0	4	0	0	1	0	14	0	**27**	**Solothurn**	**Solothurner Spitäler Bürgerspital Solothurn Kantonsspital Olten**
71	13	43	15	16	8	5	0	5	**176**	**St. Gallen**	**Kantonsspital St. Gallen Rundum Onkologie am Bahnhofpark Tumor- und Brustzentrum ZeTuP**
8	1	5	0	1	2	0	0	0	**17**	**Thun**	**Spital STS AG Thun**
2	0	11	2	1	1	2	0	0	**19**	**Thurgau**	**Spital Thurgau Kantonsspital Frauenfeld Kantonsspital Münsterlingen**
18	13	11	12	9	4	0	0	5	**72**	**Ticino**	**Istituto Oncologico della Svizzera Italiana Clinica Luganese EOC Fondazione Oncologia Lago Maggiore**
7	0	6	0	1	2	0	0	0	**16**	**Valais**	**Hôpital du Valais, Hôpital de Sion Hôpital du Valais, Spital Brig**
10	7	22	16	1	4	0	0	0	**60**	**Vaud**	**CHUV, CCAC – Centre de Chimiothérapie Anti-Cancéreuse**
14	12	15	2	3	3	0	0	0	**49**	**Winterthur**	**Kantonsspital Winterthur**
16	9	13	5	2	6	1	0	0	**52**	**Zentralschweiz**	**Luzerner Kantonsspital**
9	0	3	2	3	2	0	1	0	**20**	**Zürich Triemli**	**Stadtspital Triemli Spital Limmattal**
5	17	14	26	2	1	0	0	0	**65**	**Zürich USZ**	**UniversitätsSpital Zürich Spital Männedorf**
15	0	1	0	23	9	0	0	0	**48**	**Foreign countries**	

Publications of SAKK and cooperative groups 2017

Trial name	Trial title	Authors	Journal	IF*
Breast Cancers				
SAKK 21/12	Phase I trial of the androgen receptor modulator CR1447 in breast cancer.	Zweifel M, Thuerlimann B, Riniker S, Weder P, von Moos R, Pagani O, Bigler M, Rothgiesser KM, Pilop C, Hawle H, Brauchli P, Tapia C, Schoenfeld W, Sessa C.	Endocr Connect	2.541
SAKK 26/10	Adjuvant treatment recommendations for patients with ER-positive/HER2-negative early breast cancer by Swiss tumor boards using the 21-gene recurrence score (SAKK 26/10).	Pestalozzi BC, Tausch C, Dedes KJ, Rochlitz C, Zimmermann S, von Moos R, Winterhalder R, Ruhstaller T, Mueller A, Buser K, Borner M, Novak U, Nussbaum CU, Seifert B, Bigler M, Bize V, Vilei SB, Rageth C, Aebi S; Swiss Group for Clinical Cancer Research (SAKK).	BMC Cancer	3.265
BIG 1-98	Cholesterol, Cholesterol-Lowering Medication Use, and Breast Cancer Outcome in the BIG 1-98 Study.	Borgquist S, Giobbie-Hurder A, Ahern TP, Garber JE, Colleoni M, Láng I, Debled M, Ejlertsen B, von Moos R, Smith I, Coates AS, Goldhirsch A, Rabaglio M, Price KN, Gelber RD, Regan MM, Thürlimann B.	J Clin Oncol	20.982
IBCSG 18-98	HER2 status predicts for upfront AI benefit: A TRANS-AIOG meta-analysis of 12,129 patients from ATAC, BIG 1-98 and TEAM with centrally determined HER2.	Bartlett JMS, Ahmed I, Regan MM, Sestak I, Mallon EA, Dell'Orto P, Thürlimann B, Seynaeve C, Putter H, Van de Velde CJH1, Brookes CL, Forbes JF, Viale G, Cuzick J, Dowsett M, Rea DW.	Eur J Cancer	6.163
IBCSG TEXT & SOFT	Concurrent and sequential initiation of ovarian function suppression with chemotherapy in premenopausal women with endocrine-responsive early breast cancer: an exploratory analysis of TEXT and SOFT.	Regan MM, Walley BA, Francis PA, Fleming GF, Láng I, Gómez HL, Colleoni M, Tondini C, Pinotti G, Salim M, Spazzapan S, Parmar V, Ruhstaller T, Abdi EA, Gelber RD, Coates AS, Goldhirsch A, Pagani O.	Ann Oncol.	9.269
IBCSG	Extended adjuvant intermittent letrozole versus continuous letrozole in postmenopausal women with breast cancer (SOLE): a multicentre, open-label, randomised, phase 3 trial.	Colleoni M, Luo W, Karlsson P, Chirgwin J, Aebi S, Jerusalem G, Neven P, Hitre E, Graas MP, Simoncini E, Kamby C, Thompson A, Loibl S, Gavilá J, Kuroi K, Marth C, Müller B, O'Reilly S, Di Lauro V, Gombos A, Ruhstaller T, Burstein H, Ribi K, Bernhard J, Viale G, Maibach R, Rabaglio-Poretti M, Gelber RD, Coates AS, Di Leo A, Regan MM, Goldhirsch A; SOLE Investigators.	Lancet Oncology	26.509
EORTC 10085	Pathological characterisation of male breast cancer:Results of the EORTC 10085/TBCRC/BIG/NABCGInternational Male Breast Cancer Program.	Marijn A. Vermeulen, Leen Slaets, Fatima Cardoso, Sharon H. Giordano, Konstantinos Tryfonidis, Paul J. van Diest, Nizet H. Dijkstra, Carolien P. Schröder, Christi J. van Asperen, Barbro Linderholm, Kim Benstead, Renee Foekens, John W.M. Martens, John M.S. Bartlett, Carolien H.M. van Deurzen.	Ann. Oncol.	9.269

Trial name	Trial title	Authors	Journal	IF*
Gastrointestinal Cancers				
SAKK 41/08	Neoadjuvant radiotherapy combined with capecitabine and sorafenib in patients with advanced KRAS-mutated rectal cancer: A phase I/II trial (SAKK 41/08).	von Moos R, Koeberle D, Schacher S, Hayoz S, Winterhalder RC, Roth A, Bodoky G, Samaras P, Berger MD, Rauch D, Saletti P, Plasswilm L, Zwahlen D, Meier UR, Yan P, Izzo P, Klingbiel D, Bärtschi D, Zaugg K; Swiss Group for Clinical Cancer Research (SAKK).	Eur J Cancer	6.163
SAKK SAKK 75/02, SAKK 75/06	Recurrence Patterns and Long-Term Results After Induction Chemotherapy, Chemoradiotherapy, and Curative Surgery in Patients With Locally Advanced Esophageal Cancer.	Steffen T, Dietrich D, Schnider A, Kettelhack C, Huber O, Marti WR, Furrer M, Gloor B, Schiesser M, Thierstein S, Brauchli P, Ruhstaller T; Swiss Group for Clinical Cancer Research (SAKK).	Ann Surg.	8.98
SAKK 77/07	External beam radiotherapy for unresectable hepatocellular carcinoma, an international multicenter phase I trial, SAKK 77/07 and SASL 26.	Herrmann E, Naehrig D, Sassowsky M, Bigler M, Buijsen J, Ciernik I, Zwahlen D, Pellanda AF, Meister A, Brauchli P, Berardi S, Kuettel E, Dufour JF, Aebersold DM; Swiss Group for Clinical Cancer Research (SAKK).	Radiat. Oncol.	2.466
SAKK 77/08	Sorafenib with or without everolimus in patients with advanced hepatocellular carcinoma (HCC): A randomized multicenter, multinational phase II trial (SAKK 77/08 and SASL 29).	Koeberle D, Dufour JF, Demeter G, Li Q, Ribi K, Samaras P, Saletti P, Roth AD, Horber D, Buehlmann M, Wagner AD, Montemurro M, Lakatos G, Feilchenfeldt J, Peck-Radosavljevic M, Rauch D, Tschanz B, Bodoky G.	Ann. Oncol.	7.04
Genetic Counseling				
	Genetic predisposition to breast and ovarian cancer.	Chappuis P O , Bolligerb B, Bürkic N, Buserd K, Heinimanne k, Monneratf C, Morantg R, Paganih O, Pereyi L, Rabaglioj M, Ungerk S.	Schweiz. Ärztezeitung	
Leukemias				
GRAALL-2003/2005 GRAALL-2003/2005	Impact of cytogenetic abnormalities in adults with Ph-negative B-cell	Eichhorst B, Fink AM, Bahlo J, Busch R, Kovacs G, Maurer C, Lange E, Köppler H, Kiehl M, Sökler M, Schlag R, Vehling-Kaiser U, Köchling G, Plöger C, Gregor M, Plesner T, Trneny M, Fischer K, Döhner H, Kneba M Wendtner CM, Klapper W, Kreuzer KA, Stilgenbauer S, Böttcher S, Hallek M; international group of investigators; German CLL Study Group (GCLLSG).	Lancet Oncol.	24.69
GRAALL	Time for ALL adults tocatch up with the children.	Anthony V. Moorman.	Blood Journal	13.164
HOV-ON-SAKK	Distinct Factors Determine the Kinetics of Disease Relapse in Adults Transplanted for Acute Myeloid Leukaemia.	Craddock C, Versluis J, Labopin M, Socie G, Huynh A, Deconinck E, Volin L, Milpied N, Bourhis JH, Rambaldi A, Chevallier P, Blaise D, Manz M, Vellenga E, Vekemans MC, Maertens J, Passweg J, Vyas P, Schmid C, Löwenberg B, Ossenkoppele G, Mohty M, Cornelissen JJ, Nagler A; Acute Leukemia Working Party of the European Society for Blood and Marrow Transplantation and HOVON-SAKK.	Journal of Intern Med	7.98
Lung Cancers				
SAKK 19/05	24h-gene variation effect of combined bevacizumab/ erlotinib in advanced non-squamous non-small cell lung cancer using exon array blood profiling.	Baty F, Joerger M, Früh M, Klingbiel D, Zappa F, Brutsche M.	J Transl Med	3.694
SAKK 19/09	Bevacizumab Plus Pemetrexed Versus Pemetrexed Alone as Maintenance Therapy for Patients With Advanced Nonsquamous Non-Small-cell Lung Cancer: Update From the Swiss Group for Clinical Cancer Research (SAKK) 19/09 Trial.	Gautschi O, Rothschild SI, Li Q, Matter-Walstra K, Zippelius A, Betticher DC, Früh M, Stahel RA, Cathomas R, Rauch D, Pless M, Peters S, Froesch P, Zander T, Schneider M, Biaggi C, Mach N, Ochsenbein AF; Swiss Group for Clinical Cancer Research.	Clin Lung Cancer. 2017	3.03
ETOP BELIEF	Erlotinib and bevacizumab in patients with advanced non-small-cell lung cancer and activating EGFR mutations (BELIEF): an international, multicentre, single-arm, phase 2 trial.	Rosell R, Dafni U, Felip E, Curioni-Fontecedro A, Gautschi O, Peters S, Massutí B, Palmero R, Ponce Aix S, Carcereny E, Früh M, Pless M, Popat S, Kotsakis A, Cuffe S, Bidoli P, Favaretto A, Froesch P, Reguart N, Puente J, Coate L, Barlesi F, Rauch D, Thomas M, Camps C, Gómez-Codina J, Majem M, Porta R, Shah R, Hanrahan E, Kammler R, Ruepp B, Rabaglio M, Kassapian M, Karachaliou N, Tam R, Shames D S,Molina-Vila M A,Stahel R A.	Lancet Respiratory Medicine	15.328
ETOP BELIEF	Combined bevacizumab and erlotinib treatment in patients with lung cancer with the T790M resistance mutation.	Mitsudomi T.	Lancet Respiratory Medicine	15.328
Lymphomas				
SAKK 35/03	Rituximab maintenance improves overall survival of patients with follicular lymphoma-Individual patient data meta-analysis.	Vidal L, Gafter-Gvili A, Salles G, Bousseta S, Oberman B, Rubin C, van Oers MH, Fortpied C, Ghielmini M, Pettengell R, Witzens-Harig M, Dreger P, Vitolo U, Gomes da Silva M, Evangelista A, Li H, Freedman L, Habermann TM, Shpilberg O.	Eur J Cancer	6.163

Trial name	Trial title	Authors	Journal	IF*
SAKK 38/08	Cancer-specific geriatric assessment and quality of life: important factors in caring for older patients with aggressive B-cell lymphoma.	Ribi K, Rondeau S, Hitz F, Mey U, Enoiu M, Pabst T, Stathis A, Fischer N, Clough-Gorr KM.	Supportive Care in Cancer	2.535
SAKK 38/07	Mutations of CREBBP and SOCS1 are independent prognostic factors in diffuse large B cell lymphoma: mutational analysis of the SAKK 38/07 prospective clinical trial cohort.	Juskevicius D., Jucker D., Klingbiel D., Mamot C., Dirnhofer S., Tzankov A.	Journal of Hematology & Oncology	6.263
HD 7 - HD 12	Late Relapse of Classical Hodgkin Lymphoma: An Analysis of the German Hodgkin Study Group HD7 to HD12 Trials.	Bröckelmann PJ, Goergen H, Kohnhorst C, von Tresckow B, Moccia A, Markova J, Meissner J, Kerkhoff A, Ludwig WD, Fuchs M, Borchmann P, Engert A.	J Clin Oncol	20.982
HD 18	PET-guided treatment in patients with advanced-stage Hodgkin's lymphoma (HD18): final results of an open-label, international, randomised phase 3 trial by the German Hodgkin Study Group.	Borchmann P, Goergen H, Kobe C, Lohri A, Greil R, Eichenauer DA, Zijlstra JM, Markova J, Meissner J, Feuring-Buske M, Hüttmann A, Dierlamm J, Soekler M, Beck HJ, Willenbacher W, Ludwig WD, Pabst T, Topp MS, Hitz F, Bentz M, Keller UB, Kühnhardt D, Ostermann H, Schmitz N, Hertenstein B, Aulitzky W, Maschmeyer G, Vieler T, Eich H, Baues C, Stein H, Fuchs M, Kuhnert G, Diehl V, Dietlein M, Engert A.	Lancet Oncology	26.509
HD 18	Progression-free survival of early interim PET-positive patients with advanced stage Hodgkin's lymphoma treated with BEACOPPescalated alone or in combination with rituximab (HD18): an open-label, international, randomised phase 3 study by the German Hodgkin Study Group.	Borchmann P, Haverkamp H, Lohri A, Mey U, Kreissl S, Greil R, Markova J, Feuring-Buske M, Meissner J, Dührsen U, Ostermann H, Keller U, Maschmeyer G, Kuhnert G, Dietlein M, Kobe C, Eich H, Baues C, Stein H, Fuchs M, Diehl V, Engert A.	Lancet Oncology	26.509
Melanoma				
EORTC 18952	Long term follow up of the EORTC 18952 trial of adjuvant therapy in resected stage IIB-III cutaneous melanoma patients comparing intermediate doses of interferon-alpha-2b (IFN) with observation: Ulceration of primary is key determinant for IFN-sensitivity.	Eggermont AM, Suciu S, Rutkowski P, Kruit WH, Punt CJ, Dummer R, Salès F, Keilholz U, de Schaetzen G, Testori A; EORTC Melanoma Group.	Eur. J. Cancer.	5.42
New Anticancer Treatments				
SAKK 65/12	Phase I trial of the oral smoothened inhibitor sonidegib in combination with paclitaxel in patients with advanced solid tumors.	Stathis A, Hess D, von Moos R, Homicsko K, Griguolo G, Joerger M, Mark M, Ackermann CJ, Allegrini S, Catapano CV, Xyrafas A, Enoiu M, Berardi S, Gargiulo P, Sessa C	Invest New Drug	3.281
Outcomes Research				
Outcomes Research	Cost-effectiveness of palbociclib plus letrozole versus letrozole alone as a first-line treatment in women with oestrogen receptorpositive, HER2-negative, advanced breast cancer. Revised results for the Swiss health care setting.	Matter-Walstra K, Schwenkglenk M, Dedes KJ.	Breast Cancer Res Treat	4.08
Sarcomas				
GeDDis	Gemcitabine and docetaxel versus doxorubicin as first-line treatment in previously untreated advanced unresectable or metastatic soft-tissue sarcomas (GeDDiS): a randomised controlled phase 3 trial.	Seddon B, Strauss SJ, Whelan J, Leahy M, Woll PJ, Cowie F, Rothermundt C, Wood Z, Benson C, Ali N, Marples M, Veal GJ, Jamieson D, Küver K, Tirabosco R, Forsyth S, Nash S, Dehbi HM, Beare S.	Lancet Oncology	26.509
Urogenital Cancers				
SAKK 09/10	Impact of dose intensified salvage radiation therapy on urinary conti-nence recovery after radical prosta-tectomy: Results of the randomized trial SAKK 09/10.	Ghadjar P, Hayoz S, Bernhard J, Zwahlen DR, Stein J, Hölscher T, Gut P, Polat B, Hildebrandt G, Müller AC, Putora PM, Pa-pachristofilou A, Schär C, Dal Pra A, Biag-gi Rudolf C, Wust P, Aebersold DM, Thal-mann GN; Swiss Group for Clinical Cancer Research (SAKK).	Radiother. Oncol.	4.817
	Re: Radiation With or Without Antiandrogen Therapy in Recurrent Prostate Cancer.	Beck M, Hayoz S, Ghadjar P.	Eur Urol	14.976
STAMPEDE	Abiraterone for Prostate Cancer Not Previously Treated with Hormone Therapy.	James ND, de Bono JS, Spears MR, Clarke NW, Mason MD, Dearnaley DP, Ritchie AWS, Amos CL, Gilson C, Jones RJ, Matheson D, Millman R, Attard G, Chowdhury S, Cross WR, Gillessen S, Parker CC, Russell JM, Berthold DR, Brawley C, Adab F, Aung S, Birtle AJ, Bowen J, Brock S, Chakraborti P, Ferguson C, Gale J, Gray E, Hingorani M, Hoskin PJ, Lester JF, Malik ZI, McKinna F, McPhail N, Money-Kyrle J, O'Sullivan J, Parikh O, Protheroe A, Robinson A, Srihari NN, Thomas C, Wagstaff J, Wylie J, Zarkar A, Parmar MKB, Sydes MR.	N Eng J Med	72.406
STAMPEDE	Adding Celecoxib With or Without Zoledronic Acid for Hormone-Naïve Prostate Cancer: Long-Term Survival Results From an Adaptive, Multiarm, Multistage, Platform, Randomized Controlled Trial.	Mason MD, Clarke NW, James ND, Dearnaley DP, Spears MR, Ritchie AW, Attard G, Cross W, Jones RJ, Parker CC, Russell JM, Thalmann GN, Schiavone F, Cassoly E, Matheson D, Millman R, Rentsch CA, Barber J, Gilson C, Ibrahim A, Logue J, Lydon A, Nikapota AD, O'Sullivan JM, Porfiri E, Protheroe A, Srihari NN, Tsang D, Wagstaff J, Wallace J, Walmsley C, Parmar MK, Sydes MR; STAMPEDE Investigators.	J Clin Oncol	20.982

Trial name	Trial title	Authors	Journal	IF*
Other, Consulting				
	Absence of Evidence is not Evidence of Absence: The Case of Non-Inferiority.	Klingbiel D, Thürlimann B, Brauchli P, von Moos R.	Ann. Oncol.	9.269
	Concurrent chemoradiotherapy vs. radiotherapy alone in locally advanced cervix cancer: A systematic review and meta-analysis.	Datta NR, Stutz E, Liu M, Rogers S, Klingbiel D, Siebenhüner A, Singh S, Bodis S.	Gynecol Oncol	4.198
	Is Dose-Intensified Salvage Radiation Therapy After Prostatectomy Beneficial?	Ghadjar P, Hayoz S, Zwahlen DR, Thalmann GN, Aebersold DM; Swiss Group for Clinical Cancer Research (SAKK).	J Clin Oncol.	20.982
	In Regard to Pisansky et al.	Ghadjar P, Hayoz S, Zwahlen DR, Thalmann GN, Aebersold DM; Swiss Group for Clinical Cancer Research (SAKK).	Int J Radiat Oncol Biol Phys	4.49
	NSAID treatment with meloxicam enhances peripheral stem cell mobilization in myeloma.	Jeker B, Novak U, Mansouri Taleghani B, Baerlocher GM, Seipel K, Mueller BU, Bigler M, Betticher D, Luethi JM, Farese S, Ruefer A, Pabst T.	Bone Marrow Transpl.	3.874
	The Recombinant Bacille Calmette-Guérin Vaccine VPM1002: Ready for Clinical Efficacy Testing.	Nieuwenhuizen NE, Kulkarni PS, Shaligram U, Cotton MF, Rentsch CA, Eisele B, Grode L, Kaufmann SHE.	Front. Imunnolog.	6.429

* Impact factor

Presentations of SAKK trials (without cooperative groups)

ASCO Annual Meeting 2017 in Chicago

Poster discussion

Ruhstaller T. et al. Intergroup phase III trial of neo-adjuvant chemotherapy, followed by chemo-radiation and surgery with and without cetuximab in locally advanced esophageal carcinoma: First results from the SAKK 75/08 trial.

Poster

Joerger M. et al. A Phase 1 study to assess the safety, pharmacokinetics (PK), pharmacodynam-ics (PD) and antitumor activities of BAL101553, a novel tumor checkpoint controller (TCC), admin-istered as 48-hour infusion in adult patients with advanced solid tumors (SAKK 67/15).

ESMO 2017 congress in Madrid

Poster

Gillessen S. et al. A phase 2 trial of ODM-201 maintenance therapy in patiens with metastatic castration resistant prostate cancer (mCRPC) previously treated with a AR targeting agent and non-progressive on a second line taxane (SAKK 08/16).

Poster

Fehr M. et al. High thromboembolic event rate in patients with locally advanced esophageal cancer during perioperative therapy. A pre-planned analysis of the intergroup phase III trial SAKK 75/08.

ESTRO congress in Vienna

Oral presentation

Ghadjar P. et al. Relevance of central pathology review in prostatectomy specimens: data from the SAKK 09/10 trial.

International Conference on Malignant Lymphoma ICML in Lugano

Poster

Novak U. et al. SAKK 36/13 – Ibrutinib and bortezomib followed by ibrutinib maintenance in patients with relapsed and refractory mantle cell lymphoma: Phase I report of a Phase I/II trial.

Jahrestagung 2017 der Deutschen, Österreichischen und Schweizerischen Gesellschaften für Hämatologie und Medizinische Onkologie DGHO

Poster discussion

Ruhstaller T. et al. Intergroup phase III trial of neo-adjuvant chemotherapy, followed by chemo-radiation and surgery with and without cetuximab in locally advanced esophageal carcinoma: First results from the health economic analysis of SAKK 75/08 trial.

Poster

Fehr M. et al. High thromboembolic event rate in patients with locally advanced esophageal cancer during perioperative therapy. A pre-planned analysis of the intergroup phase III trial SAKK 75/08.

73. Jahresversammlung der Schweizerischen Gesellschaft für Urologie in Lugano

Rentsch C. et al. Results of the phase-I open-label clinical trial SAKK 06/14 assessing safety of intravesical instillation of the recombinant BCG VPM1002BC in patients with non-muscle invasive bladder cancer and previous failure to conventional BCG therapy.

World Conference on Lung Cancer WCLC in Yokohama

Oral presentation

Rothschild S. et al. CCNE1, PTGS2, TGFA and WISP2 predict benefit from bevacizumab and chemotherapy in patients with advanced non-small cell lung cancer (SAKK19/09).

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