Annual report 2014

We want the best possible cancer therapy.

SAKK

WE BRING PROGRESS TO CANCER CARE

Content

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50 years of SAKK – 50 years of progress

The history of the Swiss Group for Clinical Cancer Research (SAKK) – our national clinical cancer research network – is a success story. However, we cannot afford to rest on our laurels. Important factors will determine our future: the Swiss healthcare system is undergoing rapid change, and SAKK is adapting itself and helping to shape the transformation. Medical and pharmacological progress have forced our organization to keep on adapting and developing. This is the only way to meet the needs of patients and researchers. This is certainly nothing new, because in the 50-year history of SAKK, the only constant has been change. Our vision is the only thing that does not change: we want the best possible cancer therapy for patients.

The clinical trial landscape is altering

A total of 710 patients participated in trials in 2014; although still a high number, this was significantly lower than in the previous year (all figures are given on p. 40). One reason for this was that a number of major long-term trials were concluded and follow-up trials have not started yet. There is a growing trend towards smaller trials, prompted by ever-increasing fragmentation of the indications. Many Phase I trials are in development but few Phase III trials are in prospect. This expansion of early drug development was a strategic objective, but it also reduces the total number of new patients included in trials.

Furthermore, politicians are calling for the available funding to be spent on more research in the public interest, such as improved care. We are promoting new kinds of cooperation in an effort to achieve this.

Innovation and quality are our guiding principles

One example is the SAKK 96/12 trial: this trial is investigating whether a less frequent dose of denosumab is at least as effective as the approved standard dose. Since gaining marketing authorization in December 2011, denosumab is increasingly being used to treat patients with bone metastases. The results of SAKK 89/10 also discussed the economic aspects and showed that there are regional differences in the treatment of cancer patients at the end of their lives. Rising healthcare costs and the cost effectiveness of medical treatments present a major social challenge. SAKK wants to help find a solution by running high quality, innovative trials.

Good marks for SAKK from top experts

In order to achieve the required quality, SAKK's Management is constantly striving to improve processes. The Board is also continuing to develop its competencies, so that project proposals can be assessed in accordance with the research strategy and the Board can discharge its responsibilities. Under the terms of the service level agreement with the State Secretariat for Education, Research and Innovation (SERI), an evaluation of SAKK was carried out in 2014 under the lead management of the Swiss National Science Foundation. A top-level team of international cancer research experts examined how SAKK evaluates new trial proposals. The results provided valuable pointers on where we can improve.

Financial challenges

Less money was paid out to the centers because of the fall in the number of patients. In some cases this caused problems for our members' budgets. A comprehensive report estimated the «in kind» contributions made by the centers. It could be shown that the regulatory and administrative workload associated with clinical trials has risen significantly in recent years. The Board therefore decided to increase the contributions per patient.

Partnerships open up new opportunities

Patient-oriented research and, most recently, health services research are commonly used terms, but potential donors hesitate to commit themselves financially. Other areas of research are more attractive, even though they are less beneficial to patients. SAKK is therefore working on new financing models and promoting collaboration with partners such as Gateway for Cancer Research or the Rising Tide Foundation for Clinical Cancer Research (further information may be found on p. 26). The newly created position of Innovation & Business Development Manager will also enable the implementation and supervision of additional Phase I trials. Simona Berardi Vilei took up this post on 1 January 2015.

Exploiting the anniversary to the full

We intend to make use of our 50th anniversary to increase public awareness of SAKK. Our aim is to communicate our history, achievements and vision as widely as possible. This will engender trust in two respects: first, it motivates our employees and strengthens their sense of identity with SAKK, and second, we aim to strengthen and enhance the relationship of trust with donors, partners and the general public. We are therefore using the opportunity presented by our 50th anniversary in order to create the best possible conditions for the future and make our vision known throughout Switzerland.

Prof Dr Beat Thürlimann
SAKK President

Dr Peter Brauchli
SAKK CEO

January

New law on research comes into force

The Human Research Act with its implementing regulations comes into force on January 1. The new law is designed to guarantee the protection of participants in clinical trials and at the same time create favorable framework conditions for research. However, the implementation of the new law without a transition phase proved to be rather challenging for all involved stakeholders (see p. 22 for further details).

February

SAKK aims to improve treatment for patients with chronic myeloid leukemia

The trial CML V aims to improve treatment strategies in chronic myeloid leukemia (CML) by investigating whether patients respond better to the combination of nilotinib plus interferon alpha than to nilotinib alone (standard treatment). The trial should provide important data on the required duration of active therapy in CML patients.

Trial SAKK 69/13 activated

The trial SAKK 69/13 *Phase IB of oral BGJ398 (pan FGFR inhibitor) and oral BYL719 (a specific PI3K inhibitor) in adult patients with selected solid tumors* is activated.

March

Trial INOVATYON activated

The trial 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 is activated.

April

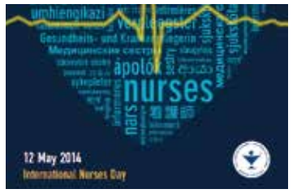
New breast cancer study SAKK 21/12 activated

SAKK started a new trial in breast cancer. It is specifically aimed at patients with hormone-dependent, HER2-negative or triple-negative and androgen receptor-positive, metastatic or locally advanced breast cancer. The trial investigates the tolerability and efficacy of the new medicine CR1447 in ointment form.

May

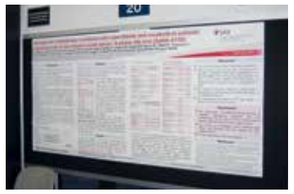
SAKK invests in further training

International Nurses Day is celebrated every year on May 12. Nurses play an important role in the SAKK network and SAKK invests in their further training. Every year, two basic training events are held for Trial Nurses or Clinical Research Coordinators who are new to clinical research or who still have little experience in trial-specific functions.



SAKK presents its research results at the ASCO meeting

The annual meeting of the American Society of Clinical Oncology (ASCO) takes place in Chicago from May 30 to June 3. SAKK was represented with four poster presentations, two of which are being discussed in a poster highlights session. In addition, the results of various international studies in which SAKK centres participated are presented at ASCO.



June

ASCO news presented in Switzerland

On June 12, speakers well-known throughout Switzerland present the scientific results of the annual meeting of the American Society of Clinical Oncology (ASCO) at the Swiss PostASCO event to an audience of specialists and experts.

SAKK summer semi-annual meeting

The cancer research network meets in Bern on June 26 and 27. Over 250 specialists and experts of the various research groups meet to discuss and develop new proposals for studies. On the eve of the semi-annual meeting, the SAKK General-Assembly takes place. The member representatives confirm *Arnaud Roth* and *Walter R. Marti* for a second term as board members.

Swiss network for clinical cancer research continues to grow

A new SAKK working group «Imaging in Diagnostics and Therapy Monitoring» is established. Johannes Heverhagen and Hendrik von Tengg, both from the Inselspital Bern, were adopted unanimously as president and president elect.

Researcher from Basel receives grant for study against chronic leukemia

The winner of the Gateway/RT F-CCR/SAKK Research Grant, endowed with USD 450'000, is Radek Skoda and his research team from the University Hospital in Basel. The research project aims at creating a novel treatment option for bone marrow cancer patients without therapy alternatives.

Young doctor from University Hospital Basel receives SAKK/Dr. Paul Janssen Fellowship

Benjamin Kasenda from the University Hospital Basel obtained the fellowship, which is jointly awarded by SAKK and Janssen-Cilag. The educational grant is aimed at offering young doctors the opportunity to spend four months at a renowned research center abroad.

July

Gateway for Cancer Research additionally funds breast cancer study

In addition to the Gateway/RTF-CCR/SAKK research grant 2014 (see above), Gateway for Cancer Research agreed to also fund the runner-up of the proposals, specifically, the grant application by Christoph Mamot from the Kantonsspital Aarau with the title «multi-center, investigator-initiated single arm phase II trial to evaluate the efficacy of anti-EGFR immunoliposomes in patients with pretreated triple-negative breast cancer».

SAKK participates in study on male breast cancer

The international EORTC 10085 trial is investigating the biological basis of breast cancer in men and the clinical course of the disease. The trial was initiated with the aim of gaining a better understanding of the clinical and pathological characteristics of this disease. This should assist in the definition of future treatment options for men with breast cancer.

Trial SAKK 15/12 for patients with small-cell lung carcinoma activated

The standard treatment of small-cell lung cancer consists in thoracic radiotherapy combined with chemotherapy. About 50% of patients develop brain metastases in the course of their disease. The aim of this trial is to study the effects on cognitive functions during this early preventive whole-brain irradiation carried out at the same time as standard therapy.

New trial SAKK 96/12 for patients with bone metastases activated

Bone metastases – the spread of cancer to the bones – are a frequent complication in patients with advanced cancer. The project SAKK 96/12 is designed to show that less frequent dosing of Xgeva® is at least as effective as the approved standard dosing regimen. The trial SAKK 96/12 is being carried out in collaboration with the health insurers.

September

Orphan Malignancies Seminar

On September 18 a multidisciplinary faculty of Swiss experts including surgeons, radiation oncologists, pathologists and oncologists gathered in Zürich to discuss the management of patients with thymic neoplasms and the optimal treatment of small cell lung cancer.

SAKK presents its research results at the ESMO congress

The 2014 congress of the European Society for Medical Oncology (ESMO) takes place in Madrid. SAKK was represented with two oral presentations, one poster discussion and three poster presentations.

October

New study on the exploration and validation of biomarkers for prostate cancer

In the SAKK 63/12 study, a multicentre biobank of patient sera is being established together with information of relevance to the disease, in order to provide a basis for the testing of biomarkers. The aim is to identify markers that offer diagnostic and treatment-selective markers and thus make a decisive contribution to the optimum care of patients.

November

SAKK winter semi-annual meeting

The meeting takes place in St.Gallen on 20 and 21 November. The convention also offers the opportunity for further training and the participation in scientific symposia. At the winter meeting, the GIST award by the Swiss GIST group as well as the Candy Heberlein Research Award of the Foundation for the Advancement of Bone Marrow Transplant Switzerland (SFK) were awarded.

New member of the SAKK board

Michele Ghielmini stepped down as a board member and the General Assembly unanimously elected Cristiana Sessa as his successor.

December

New trial for patients with advanced multiple myeloma

Despite the recent advances in myeloma treatment, this disease remains incurable. During the course of the disease, almost all patients become resistant to the therapy. The trial SAKK 39/13 evaluates a new type of combination of drugs for the treatment of bortezomib-resistant advanced multiple myeloma.

Better integration of patients in research

On December 11, representatives of patient organizations, authorities, academic research and the pharmaceutical industry met in Bern for a workshop to discuss how the concerns of patients can be better integrated in research. The aim of the conference in Bern was to bring together interested organizations from Switzerland and to create conditions for the establishment of a national organization in the framework of the EUPATI platform.

By Dr Christian Taverna
Medical Director of Oncology
Münsterlingen Cantonal Hospital

Meet a SAKK member

Spital Thurgau AG (STGAG), which includes the cantonal hospitals of Münsterlingen (KSM) and Frauenfeld (KSF) as well as Thurgau Psychiatric Services and the St. Katharinental rehabilitation clinic, carries out oncological treatment in the two cantonal hospitals. Spital Thurgau AG's catchment area covers the Canton of Thurgau, which has a population of about 260,000.

Weekly Tumour Boards ensure communication

The Canton of Thurgau has its own Ethics Committee. The various weekly Tumour Boards of the two cantonal hospitals have taken place jointly via video conference for a number of years. The following disciplines actively participate in them: medical oncology, haematology, radio-oncology, surgery, gynaecology, diagnostic and interventional radiology, nuclear medicine, pathology, urology, orthopaedics, plastic surgery, pulmonology, gastroenterology, palliative care, neurosurgery. This means that a wide spectrum of tumour treatments can be covered.

Clinical research is a key part of everyday life in hospitals

A large number of doctors who are now represented on the Tumour Boards have already made an active previous commitment to SAKK's various project groups. Participation in clinical trials was always very important to them. For many years now, patients have also been involved in SAKK and IBCSG studies in Münsterlingen and Frauenfeld. Clinical research activity has increased steadily in recent years. In order to further boost its commitment, the center applied for SAKK membership in 2013. The following clinics and departments are involved in clinical research in oncology:

- Oncology/Haematology Münsterlingen Cantonal Hospital
- Oncology Frauenfeld Cantonal Hospital
- Radio-oncology Münsterlingen Cantonal Hospital
- Frauenfeld Women's Hospital and Thurgau Breast Care Centre

The trials are supported by four study coordinators (2.1 full-time equivalents).

Focus on efficiency and treatment quality

Following the acceptance of Spital Thurgau AG as a SAKK member, we are able to contribute to the discussion on SAKK's research priorities and build dialogues and partnerships with other members. In this respect it is important that the concerns of the smaller centers are also represented. The constructive discussions with the trial coordinators and monitors at SAKK, and the dialogue with trial managers at the regular SAKK meetings, have produced additional suggestions on how to optimize structures and processes when conducting trials. With this focus on efficiency and treatment quality, we can increase our commitment to clinical cancer research, provide our patients with the optimum therapy and maintain high motivation in the trial teams.

As an active member of SAKK, we can offer cancer patients in the Canton of Thurgau access to high-quality clinical trials. Spital Thurgau AG wants to continue to contribute to clinical researsch and live the SAKK vision: the best possible cancer therapy for patients.

50 years of commitment

Claudia Herren / Communications Manager

Until the 1950s, almost nothing could be done to slow down or stop cancer. Since then, there has been a significant improvement in the situation. Today, cancer can frequently be cured, often using an interdisciplinary approach. The progress of the disease can often be slowed down, the severity of its side effects lessened and pain reduced. There are now effective treatments for many types of cancer, and survival times are increasing.

The diagnostic aids available today allow tumours to be classified more precisely and cancer treatments to be tailored to individual patients more effectively. Today, the focus of clinical cancer research is therefore on personalized treatments rather than broad-spectrum therapies. The experience of the past 50 years clearly shows that when different therapy options are used at the same time, the resulting combination therapy can be very beneficial to patients. The challenge lies in finding the best combination of active substances for each particular patient. However, clinical trials for such targeted treatments involve a substantial investment of time and money, and this makes it all the more important to collaborate in multidisciplinary research networks such as SAKK, since it is the only way such trials can succeed.

Founder Members of SAKK


Georg Martz


Hans-Jörg Senn


Kurt Brunner


Pierre Maurice

After all, more than 35,000 people in Switzerland are still diagnosed with cancer every year, and more than 15,000 die of the disease. As Franco Cavalli, former SAKK president and Scientific Director of the Oncology Institute of Southern Switzerland, says: «We are finding out more and more about cancer and getting better and better at treating it. However, there will always be cancer and, as life expectancy rises, the number of cases of cancer in Switzerland can be expected to increase in future. That's why cancer research is more necessary than ever.»

Over the past 50 years, SAKK has developed from a small group of four people to an organization with 70 employees and 19 member centers. Its goal nevertheless remains the same:

«We want the best possible cancer therapy for patients»

The example of breast cancer:

For a long period there was only one effective treatment for breast cancer: the removal of the entire breast, a procedure that was often traumatic for patients. In the 1960s, European surgeons were looking for a less radical but equally successful treatment. A surgical technique was developed that no longer involved amputation of the entire breast. Meanwhile, a less radical procedure for axillary surgery became established and new methods against breast cancer were developed, with the introduction of a number of modern drugs, for example. Today, good results can be achieved in breast reconstruction thanks to plastic surgery.

A brief history

1965 The Swiss Chemotherapy Group is founded under the direction of **Kurt W. Brunner**, as the precursor of what is now SAKK.

1971 The Chemotherapy Group becomes the Swiss Group for Clinical Cancer Research (SAKK) – the change of name reflecting the multidisciplinary nature of the Group (surgery, radiotherapy, chemotherapy).

1975 Professor Pierre Alberto becomes president of the group. Under his leadership, SAKK finds its first permanent home in Rue Carouge in Geneva.

1981 Professor Franco Cavalli becomes president of SAKK. The name SAKK enjoys great prominence and the publication of crucial studies in the fields of leukemia, colon cancer and breast cancer carry the name SAKK out into the world.

Professor Hans-Jörg Senn becomes president of SAKK in **1988**. More than anyone else, Hans-Jörg Senn shapes international collaboration with the IBCSG and is regarded as the pioneer of Swiss breast cancer research.

At the same time as **Professor Urs Metzger** becomes president in **1991**, the Swiss Institute of Applied Cancer Research (SIAK) is founded. The idea is to combine SAKK, SPOG (paediatric oncology) and VSKR (Association of Swiss Cancer Registers) into a single point of contact for the federal authorities on matters related to patient-oriented cancer research.

1994 Professor Aron Goldhirsch becomes president of SAKK. He sets consistent scientific standards for clinical research and the transfer of results to the clinical setting. He remains in office for 10 years.

The introduction of the Therapeutic Products Act in **2002** throws a number of obstacles in the path of SAKK. The future is discussed at a meeting of center directors in Zurich in **2004**. Professor Richard Herrmann agrees to take over the vacant presidency.

SAKK becomes independent again: at the meeting in **autumn 2007** the delegates agree to a merger between SIAK and SAKK. This leads, after 16 years, to the integration of the existing SIAK organization into the merger partnership, which is continued under the name SAKK.

In **2010 Professor Beat Thürlimann** takes over as president from Richard Herrmann. SAKK faces increasing challenges in terms of research policy and the development of personalized healthcare.

2015 In recent years, SAKK's Coordinating Center in Bern has developed into a center of excellence for the national and international organization of clinical trials.

The example of testicular cancer:
Thanks to chemotherapy, it is now possible to prevent metastasis, either partially or completely. A prime example is aggressive testicular cancer. Previously the actual cancer was removed surgically, yet most young men died from this fast-spreading disease within six months. Today, testicular cancer is 90% curable, including at the advanced stage in most cases.

Severin Strasky
Head of Fundraising & Communications

Why donations help patients

As part of the strategic partnership between Gateway for Cancer Research (a non-profit organization based in the USA), the Rising Tide Foundation for Clinical Cancer Research (a foundation based in Switzerland), and SAKK, in 2014 the Gateway/RTF-CCR/SAKK research prize for outstanding and novel clinical cancer research was awarded for the second year in succession. The winner of the research award, which is worth USD 450,000, was announced at the SAKK semi-annual meeting in June 2014. Professor Radek Skoda, Basel University Hospital, and his research group won the award for their project, which offers the prospect of a new treatment option for bone marrow cancer patients, for whom no alternative therapies are available.

New charities show confidence in SAKK
New charities, as well as long-term partners, have demonstrated their trust in SAKK: five foundations have decided to co-fund a SAKK trial. We very much appreciate the confidence they demonstrate in us.

Innovative trial wins Grant for Oncology Innovation
Which trial is best suited to the funding aims of a donor? This is a key question for fundraising, and it is not always an easy task to select the right trial from the complete SAKK portfolio.

However, it was successfully achieved in the case of the SAKK 41/13 trial. In January 2014 the SAKK Board approved the trial on condition that a quarter of its entire costs must be provided through third-party funding; only then would the trial be activated. SAKK sought and contacted suitable backers – successfully – in cooperation with the trial team led by Ulrich Güller and Markus Jörger. This innovative trial, the aim of which was to examine adjuvant aspirin treatment in colorectal cancer, won the Merck Serono Award «Grant for Oncology Innovation (GOI) 2014» and was able to attract support from the Swiss National Science Foundation. In just nine months these substantial contributions made it possible to surmount the financial hurdles set by the SAKK Board and start developing the trial.

U. Güller, M. Jörger

Dr Claudia Weiss
Development & Politics

Political activities

SAKK helps implement the National Strategy Against Cancer
The National Strategy Against Cancer 2014–17 turns the priorities defined in the National Cancer Programme 2011–15 into specific projects. It is aimed to implement these projects as part of the fight against cancer. Various organizations and institutions are currently working intensively on these ten major projects and sub-projects. SAKK has assumed a leading role within the «Clinical and translational research» project cluster. The «Human Research Act» working group, for example, has set itself the goal of analysing the introduction of the legislation and defining measures to press ahead with the planned practical implementation. Another subproject examines ways of making clinical research more attractive to researchers and develops suggestions for long-term research programmes in oncology. This working group is led by Swiss Cancer Research and supported by SAKK.

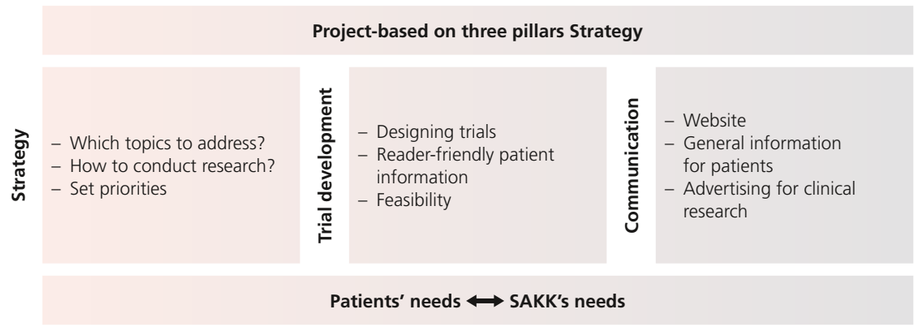
National law on cancer registration
In line with the priorities set for public health policy, the Federal Council sent the first draft and the corresponding dispatch on the registration of cancer to the Swiss parliament at the end of October. The new law is intended to ensure the creation of a basis of data that can be used for the purpose of formulating prevention and early diagnosis measures, assessing the quality of care, diagnosis and treatment, supporting cantonal care planning and conducting research into cancer. The draft bill regulates various aspects of cancer registration, including the collection, registration and transmission of data for evaluation and publication at national level. Under the umbrella of Oncosuisse (the Swiss Cancer Organization), SAKK, together with the Swiss Cancer League, NICER, the Swiss paediatric oncology group SPOG and the children's cancer register, helped draft the bill. However, the current version still takes insufficient account of researchers' concerns. In conjunction with the above-mentioned organizations, and under the overall leadership of NICER, in 2015 SAKK will work to ensure that the interests of the researchers are implemented in the legislation.

Achieving greater patient involvement in clinical research
Patient involvement is becoming increasingly important in the world of research. Patients themselves and their families are a valuable resource for understanding cancer and how to deal with it. They are familiar with the problems and needs that arise during and after the treatment of an illness and know what it means to live with the restrictions imposed by the disease. They take part in clinical trials and are best placed to judge whether the information about them is comprehensible, and they can report on which aspects of treatment and after-care could be improved from the patient's point of view. Last but not least, it is often patients who encourage and hearten other sufferers. SAKK has therefore developed a concept in which patients or representatives of patient organizations can contribute their knowledge and experience under the three pillars of Strategy, Trial Development and Communication. In order to ensure that patients' voices are heard, there are plans to set up a patient consortium (consisting of 3 to 5 people) which will be available for the Board, the Coordinating Centers and the project/section groups to consult. This body is expected to commence work in mid-2015 and to be fully established by the end of 2016.

SAKK is a key partner in the field of Highly Specialized Medicine (HSM)
The HSM specialist group prepared a report entitled «Highly specialized treatment of rare cancers in adults» which was submitted to interested parties for consideration in December 2012. This report encountered widespread rejection. SAKK was consequently asked to help.

What strategy do the experts in the SAKK network recommend?
The initial concept defines the structure and process qualities that must be present before a rare cancer can be treated at a tumour center or hospital network. Here, the focus is as much on increased cooperation and knowledge sharing between the hospitals as it is on clearly establishing which center defines the treatment strategy and where treatment is actually to take place. Binding guidelines that clearly regulate cooperation are a basic requirement for such collaborations. Greater attention will also be paid to aspects of after-care, palliative care and psychological care. In turn, closer networking between different hospitals and the clear definition of a therapy by a center of excellence allows a larger number of candidate hospitals that can treat the disease ap-propriately and possibly also take part in clinical research projects.

What happens next?
In four follow-up mandates, the working group defined the process and structure qualities for other areas in detail, with the consent of the SAKK Gen-



eral Assembly. Furthermore, it also drafted a separate document on the general principles and requirements for an interdisciplinary Tumour Board. This describes the structure, composition and qualifications of the Tumour Board in detail and defines the procedure, documentation and follow-up of meetings and treatments. In 2015, the «sarcomas» and «hyperthermic intraperitoneal chemoperfusion (HIPEC)» areas will be finalized to complete the four-part follow-up project. The reports on neuro and visceral oncology were completed at the end of 2014 and presented to the HSM specialist group.

Projects from the service level agreement with SERI

SAKK receives an annual grant of around CHF 5.5 million from the Confederation. This support is based on a service level agreement between the State Secretariat for Education, Research and Innovation (SERI) and SAKK. Most of this money is directly spent on SAKK's clinical cancer research, but it is also tied to a small number of organizational mandates. For example, at the end of 2014 SAKK drafted a detailed research strategy which will be revised again in 2015 and incorporated into an overall strategy. This overall strategy enables the Board and the Management to lead SAKK as a target-oriented enterprise.

In another project, SERI tasked SAKK and the Swiss Clinical Trial Organization (SCTO) with evaluating how both organizations can jointly contribute to national infrastructures that can be used by all academic researchers irrespective of the indication and clinical issue. SAKK conducted thorough analyses and defined core competencies which it can offer as a service to researchers, in-cluding non-oncological researchers. The next steps are currently being planned with the SCTO and implementation is due to start by 2017.

Following the introduction of the completely revised Federal Act on the Promotion of Research and Innovation at the start of 2014, government-aided research organizations must disclose any contributions they receive from third parties, including those made in the form of materials or personnel. SAKK has therefore been given the specific task of calculating the contributions that it receives from third parties in a form other than direct payment and documenting them in a short report. After making a complex calculation with the assistance of experts from the network as well as internal employees, SAKK calculated that non-cash benefits received from the hospitals for clinical cancer research amounted to CHF 7.4 million.

The Swiss National Science Foundation (SNSF) also assessed SAKK with the help of an international team of advisors, subjecting the organization to a detailed analysis of its structure, processes, project evaluation and finances. The evaluation team warmly praised SAKK for its work. In particular, the activity of the Coordinating Center on behalf of the network was much appreciated. According to the assessment by the team of experts, SAKK functions very efficiently and is thus able to make an important and internationally recognized contribution to improving cancer treatments. In addition, the assessment made important suggestions as to how SAKK should develop and position itself in the next few years.

Project group breast cancers

President: PD Dr Thomas Ruhstaller, Breast Center St.Gallen

Increase of SAKK trial activities
In 2014, the breast group recruited a total of 296 patients into clinical trials, which corresponds to an increase of 19% compared to 2013 and 55% to 2012. This is exceptional as only four out of all accrued patients were included in IBCSG trials. Hence, the loss of adjuvant IBCSG trial activities was compensated with SAKK trial activities.

Practice changing results
The results of the IBCSG-trials TEXT (Tamoxifen und Exemestane) and SOFT (Suppression of Ovarian Function) were presented by Olivia Pagani at the Meeting of the American Society of Oncology ASCO in the plenary session. Subsequently, they were published online in the New England Journal of Medicine.

The results of the IBIS-II trial were mentioned in the ASCO annual review 2015 «Advances in Oncology» as «practice changing». In the IBIS-II trial, 5 years of anastrozole therapy reduced the risk of primary breast cancer by more than 50% in women at high risk of developing the disease. It was also interesting that patients on anastrozole in this trial had a lower incidence of any malig-nancy, not just breast cancer.

Research in rare forms of breast cancers
At the moment, SAKK has five breast cancer trials open for the enrolment of patients. SAKK also conducts research in rarer forms of breast cancer, as for example breast cancer in men. Approximately 40 men in Switzerland are newly diagnosed with breast cancer each year. SAKK participates in the international EORTC 10085 study that is investigating the biological basis of breast cancer in men and the clinical course of the disease. The study was initiated with the aim of gaining a better understanding of the clinical and pathological characteristics of this disease. This should assist in the definition of future treatment options for men with breast cancer.

Project group gastrointestinal cancers

President: Dr Michael Montemurro, Instituto oncologico della Svizzera Italiana Bellinzona

St. Gallen researchers receive research award
Ulrich Güller and Markus Jörger from the Department of Oncology & Haematology at the Cantonal Hospital St. Gallen have received the Merck Serono award «Grant for Oncology Innovation (GOI) 2014». They received the research award for the trial SAKK 41/13 «Prospective double-blinded, placebo-controlled, randomized trial of adjuvant aspirin treatment in PIK3CA mutated colon cancer patients», which is being conducted at centres of the SAKK network. The project, which was selected from 143 applications submitted from 25 different countries, is now receiving support to the tune of 300,000 euros.

Project group leukemia

President: PD Dr Georg Stüssi, Instituto oncologico della Svizzera Italiana Bellinzona

New trial for patients with myeloproliferative neoplasms
The group developed an investigator-initiated SAKK phase II trial which aims to understand the biological effect of mirabegron, a beta-sympathomimetikum, on the hematopoietic niche in patients with myeloproliferative neoplasms. The trial SAKK 33/14 is of importance for the group as it is developed by Swiss investigators and it opens up a field for a new activity, as patients with myeloproliferative neoplasms have so far never been studied within SAKK.

Hope of improvement of treatment strategies
After a longer period without trials for patients with chronic myeloid leukemia (CML), the CML V study has been opened in all centers in Switzerland. The trial aims to improve treatment strategies in CML by investigating whether patients respond better to the combination of nilotinib plus interferon alpha than to nilotinib alone (standard treatment). Patients have already been included in both arms of the trial. The trial should provide important data on the required duration of active therapy in CML patients.

Project group lung cancer

President: PD Dr Oliver Gautschi, Cantonal Hospital Lucerne
Vice-President: PD Dr Solange Peters, University Hospital Vaud (CHUV)

Main focus: multimodality therapy with curative intent
The results of two randomized trials were reported at the ESMO annual meeting in Madrid. Miklos Pless presented the final results of SAKK 16/00, demonstrating excellent overall survival in patients with surgically resected non-small cell lung cancer (NSCLC) stage IIIA and neoadjuvant chemotherapy, irrespective of preoperative radiotherapy. A first manuscript was accepted for publication in the Lancet journal. A follow-on protocol in the same indication with immunotherapy was approved by the SAKK board (SAKK16/14).

The second pivotal trial, SAKK17/04, was also presented in Madrid by Rolf Stahel. Again, patients with radically resected pleural mesothelioma and neoadjuvant chemotherapy had an encouraging survival rate, irrespective of radiotherapy.

Personalized medicine
Interesting translational data from the SAKK 19/09 trial were presented at the European Lung Cancer Conference 2014 and ESMO 2014. A wide array of biomarker-based trials sponsored by ETOP and industry are currently discussed and lined-up in the national network of the project group. Open centers are listed in the new trial radar, posted in the member section on the SAKK website. We anticipate from this information platform improvements in research coordination, and also in patient referral.

Project group lymphoma

President: PD Dr Emanuele Zucca, Oncology Institute of Southern Switzerland (IOSI) Bellinzona

Leading role in chemotherapy-free treatment
A highlight was the oral presentation of the first primary endpoint analysis of the SAKK 35/10 trial results at the American Society of Hematology Annual Meeting in San Francisco. This randomized phase-2 trial was conducted by SAKK in collaboration with the Nordic Lymphoma Group (NLG) and showed that rituximab plus lenalidomide improves the complete remission rate in comparison with rituximab monotherapy in untreated follicular lymphoma patients. This trial confirmed the leading role of SAKK in the study of chemotherapy-free treatment approaches and underscored the auspicious potential of the collaboration with the Nordic Lymphoma Group in this setting.

Another major achievement of the group was the development of the follow-up trial SAKK 35/14. It will again be conducted in collaboration with the Nordic Group and will explore the role of the combination of ibrutinib and rituximab as initial treatment of follicular lymphoma patients.

Long awaited trial for relapsing mantle cell lymphoma
The long awaited trial SAKK 35/14 for relapsing mantle cell lymphoma is testing the combination of ibrutinib (a tyrosine kinase inhibitor) and bortezomib. SAKK will be the only group worldwide to have the opportunity to test this promising combination in a clinical trial.

Project group New Anticancer Drugs

President: Prof Dr Cristiana Sessa, Oncology Institute of Southern Switzerland (IOSI) Bellinzona

Participation in two first in human trials
The group activated two first in human trials. SAKK 67/13 with the accrual of 16 patients in four centers, and SAKK 21/12 with the accrual of 11 patients in six months (trial titles on p. 37). The latter will continue into an expansion phase in the breast cancer project group with a planned accrual of approximately 100 patients.

New system for the referral of patients for phase I and rare disease trials
A concept for patients referral among the active centers is in preparation and will be implemented in 2015. Responsible for this concept is Simona Berardi Vilei, Innovation and Business Development Manager at the SAKK Coordinating Center.

Project group urogenital cancers

President: Dr Richard Cathomas, Cantonal Hospital Graubünden

Successful publication of results
The results of the trial SAKK 08/09 were published in European Urology in 2014 and Arnoud Templeton presented a poster of the results of SAKK 96/12 at the ASCO annual meeting in Chicago (trial titles on p. 37).

Group members won Pfizer Prize
Results of the trial SAKK 06/98 comparing the efficacy of two different BCG strains in the treatment of non-muscle invasive bladder cancer have been published in the European Urology. The trial was conducted from 1998 to 2003 in the framework of the SAKK network.The work was elected as the best scientific publication in 2014 of the European Urology Journal and the authors Cyrill Rentsch and Frédéric Birkhäuser won the Pfizer Prize 2015 thanks to it.

Working group gynecological cancers

Presidents: Prof Dr Cristiana Sessa, Oncology Institute of Southern Switzerland (IOSI) Bellinzona
PD Dr Mathias Fehr, Cantonal Hospital Frauenfeld

Membership at ENGOT (European Network of Gynecological Oncology Trials Groups)
The group was accepted as an active member of the ENGOT network and started to include 14 patients in European studies (MITO16 and INOVATYON, see p. 35 for details). Participation to ENGOT means not only high quality studies and treatments for patients but also international recognition of the expertise of the SAKK working group.

Working group Sarcoma

Dr Christian Rothermundt, Cantonal Hospital St.Gallen

New platform to collect clinical data of sarcoma patients
The Sarcoma Working Group met twice this year and we had fruitful discussions with Rick Haas, The Netherlands Cancer Institute Amsterdam, about the role of radiotherapy in retroperitoneal soft tissue sarcomas. Activities of the Swiss National Sarcoma Board are ongoing and most of the group members are involved in setting up a platform to collect clinical data of sarcoma patients and sarcoma tissue in a next step.

Section radio-oncology

President: PD Dr Ludwig Plasswilm, Cantonal Hospital St.Gallen

The group contributed to the fast accrual of trial SAKK 09/10 and of trial SAKK 01/10.

New study for patients with small-cell lung carcinoma
The group collaborated with the lung group in the activation of the SAKK 15/12 trial for patients with small-cell lung carcinoma. The standard treatment of small-cell lung cancer consists in thoracic radiotherapy combined with chemotherapy. Approximately 50% of patients develop brain metastases in the course of their disease. Results from a study have shown that overall survival and disease-free survival of patients was improved and the occurrence of brain metastases reduced when preventive whole-brain irradiation (excluding the hippocampus region) was administered concurrently thoracic radiotherapy and chemotherapy. The aim of this trial is to study the effects on cognitive functions during this early preventive whole-brain irradiation carried out at the same time as standard therapy.

Network for Cancer Predisposition Testing and Counseling (CPTC)

President: PD Dr Pierre O. Chappuis, University Hospital Geneva (HUG)

«Angelina Jolie effect» still generates increased numbers of referrals
Eighteen centers provide genetic counseling and evaluation for cancer predisposition genetic testing throughout Switzerland. The so-called «Angelina Jolie effect» (Spring 2013) has been long-lasting and global, and appeared to have increased referrals to genetic centers worldwide and DNA tests appropriately. In many Swiss centers, more than 50% increase in consultation and BRCA1/BRCA2 testing has been observed.

Network for Outcomes Research

President: Prof Dr Bernhard Pestalozzi, University Hospital Zurich

End-of-life care of cancer patients varies from region to region
Trial SAKK 89/09 showed that the care cancer patients receive in the last month of life depends on where they live, how they are insured, how old they are and what type of cancer they are suffering from. This SAKK study was carried out in collaboration with the European Center of Pharmaceutical Medicine (ECPM) at the University of Basel, the health insurer Helsana and cantonal cancer registers.

In Switzerland there are substantial differences in the care of cancer patients during the last month of life. For example, they are not treated equally often with chemotherapy in every canton. It also depends on where they live, whether they spend the last month of life at home or are admitted to hospital. Aside from the regional differences, the treatment is also influenced by whether a patient has supplementary insurance cover. The age of the patient and the type of cancer also play an important role. The results of the study have been published in the journals BMC Cancer and Oncology (see p. 44 for details).

Dr Peter Durrer
Head of Quality Assurance & Regulatory Affairs

Christoph Kolb
Head of Clinical Trial Management

	2014	2013
Total patients from Switzerland	608	837
Total patients from foreign countries	102	169
Total	**710**	**1006**

	Patients 2014	Studies 2014	Patients 2013	Studies 2013
Total patients in SAKK-trials	517	23	551	24
Total patients in trials of cooperative groups (without IBCSG)	189	20	405	20
Total patients in IBCSG trials	4	2	50	2
Total	**710**	**45**	**1006**	**46**

Retrospektive studies, cohort studies & biobanks	Patients
EORTC 10085 PRO	11
T-Cell Project	5
SAKK 63/12	32
Total	**48**

Eleven new trials activated

A total of eleven new trials were activated in 2014. Six of these were developed by SAKK as its own study protocols and originate from our project groups for urogenital tumours, lung cancer, breast cancer, lymphomas and new anti-cancer drugs. A further five trials are spread between the breast cancer and leukemias project groups and the working group on gynaecological tumours, and are study protocols from foreign cooperative groups that have established partnerships with SAKK, some of which have been in place for many years. In this way our SAKK centers, and thus Swiss patients, obtain additional cancer therapy options, often for very rare indications. A further, fully developed SAKK trial by the project group for urogenital tumours had to be halted before activation owing to the withdrawal of its external funding.

In view of the extra resources that have had to be spent on adjusting internal processes to take account of the new Human Research Act, the number of newly activated trials is encouraging. We expect this number to rise in 2015, by which time the processes should be better established.

Indication areas are becoming increasingly specific

The number of patients recruited in 2014 (710) was significantly lower than the figure for the previous year. This is partly because some of the major, easy-to-recruit Phase III trials reached the end of their recruitment periods. Another reason is that the indication areas for oncology are becoming increasingly specific, with the result that the target populations are becoming smaller. This makes us all the more pleased at the successful opening of the major SAKK 96/12 trial for improving the treatment of bone metastases in breast and prostate cancer, which has already seen good levels of patient enrolment.

Conducting trials requires accurate planning

Project management is playing an increasingly important role in the conduct of clinical trials. The complex and at times overlapping processes require accurate, careful planning. The more complex and multicentric the trial, the more complicated this stage will be. In order to cope with these increasing demands, the job profiles of the project managers in the Clinical Trial Management (CTM) Department have been revised. Furthermore, following an in-depth, cross-functional analysis carried out jointly with an external service provider, the first phase of a trial and project management system was programmed and released for testing at the end of the year. Other modules will follow in stages, according to their priority, to ensure that trial projects can be managed efficiently in the future using an adaptable system, and that all the people and bodies involved (including project teams, SAKK Coordinating Center, Management, Board and members) can be provided with customized reports.

Focus on risk-based monitoring

In our highly regulated environment, more and more attention is being paid to the topic of risk-based monitoring. Major international regulatory authorities such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are also increasingly calling for risk-based methodology in clinical monitoring. Unlike traditional monitoring, in which almost 100% of the source data (patient files and other documents relevant to the trial) is verified at the trial center, there is now a trend towards restricting full verification to critical areas (e.g. patient safety, end-points, medication). Other areas are checked less intensively or less frequently. In turn, trial centers which can be shown to deliver consistent good quality are subject to less monitoring, whereas centers which need to improve would be visited more often. The members of SAKK's CTM monitoring team have been working on this for some time. They have already aligned some of their processes and will continue their task. In addition, there are plans to place the risk-based working method on an overarching basis which includes not only monitoring but also risk-based trial management, expanding it to cover interface functions such as data management, statistics and project management.

Inspection produces useful findings

Swissmedic has been systematically conducting regular GCP and pharmacovigilance inspections since 2010. In 2011, the SAKK network was inspected for the first time, with two SAKK centers and the Coordinating Center being visited. The first routine inspection of the SAKK Coordinating Center took place in the previous year. The inspection focused on the following two areas: first, there was an intensive review of whether all the deficiencies identified in the initial inspection had been fully corrected by the deadline. Next, three Phase I trials were evaluated, to check whether we had implemented proper and appropriate measures for conducting trials with an elevated risk potential. This external audit of our work resulted in a positive outcome. Swissmedic was able to assure itself that we had implemented all the necessary corrective measures on schedule since the initial inspection. We also have appropriate processes, sufficient experience and the right infrastructure to conduct Phase I trials. The inspection also provided valuable pointers as to where we can improve. The corrective measures required have already been implemented or will be introduced in the near future. The efforts of all SAKK employees contributed to strengthening Swissmedic's confidence in the work of SAKK.

Qualification of SAKK trial centers to conduct Phase I trials

Conducting Phase I trials, especially trials involving new drugs or treatments that are being tested on human beings for the first time, requires additional, preventive safety measures in order to provide the best possible protection for participating patients. An important prerequisite here is that such trials should be conducted at centers that are suitable for this purpose. This includes the presence of sufficiently qualified and experienced staff, appropriate infrastructure and the implementation of processes suited to high-risk trials. In order to be able to meet these conditions, the SAKK Board agreed to carry

out Phase I qualification audits at centers interested in conducting SAKK trials of this kind. This course of action was approved by the SAKK General Assembly at the end of 2013 and the qualification process started in January 2014. By the end of 2014, a total of five trial centers had been qualified to conduct Phase I trials in which a therapy is being tested on human beings for the first time. Further centers will be added in the course of 2015. Study centers that have already been qualified will be audited every two to three years to ensure that the required quality standards are still being met.

New Human Research Act (HRA)

The introduction of the new Human Research Act on 1 January 2014 substantially altered the regulatory requirements for conducting clinical trials and research projects. This has significantly increased the administrative challenges faced by researchers. The procedures have fundamentally changed in that the ethics committees have been given greater weight and Swissmedic is focussing more on inspections. As a result of the new law, SAKK has also adapted its processes and expanded its Regulatory Affairs team. The most striking change is that submissions to the ethics committees and Swissmedic are now handled centrally via the SAKK CC. Previously, major elements of the submission process were carried out on a decentralized basis via the participating trial centers. Administrative tasks have thus been centralized and the fees payable to the authorities are now borne directly by the Coordinating Center.

Obstacles during implementation

The introduction of the new law did not go smoothly for all those affected, causing a considerable amount of extra work, especially at the beginning before the new processes became established. Applications to the ethics committees for approval for multicentric clinical trials were hit particularly hard. Reviews by the ethics committees took considerably longer than had been envisaged by the legislator. The situation improved after approximately one year. Some initial conclusions can now be drawn regarding the new law. The Human Research Act is essentially a good law, but it has not been possible to implement it adequately because it is exposed to the federalist forces in Switzerland. Individual ethics committees are therefore under no obligation to implement harmonized processes and make uniform decisions. We hope that in the future, the ethics committees will increasingly work together and standardize their processes. This could be assisted by the planned imple-mentation of a joint software solution for the submission and administration of trial documentation.

Dr Dirk Klingbiel
Head of Statistics

Successful publications in reputable journals

Last year, several publications concerning SAKK trials or collaborations achieved prominence: The main publication for SAKK 08/09 appeared in January in *European Urology* and the principal report on SAKK 92/08 in *The Breast*. A further ten publications on secondary analyses and sub-projects were published, including in the *JNCI* and the *Annals of Oncology*.

The «Outcomes Research» working group also achieved success with three publications, including one on SAKK 89/09. SAKK affiliates also contributed to several major international publications, e.g. on the STAMPEDE, IBCSG, CML, GRAALL, IBIS and EORTC trials. One of the highlights in this respect was definitely IBCSG 24-02/25-02, which appeared in the *New England Journal of Medicine*.

Successful presence at international oncological congresses

SAKK was also well represented at the major international congresses: four posters were displayed at the Annual Meeting of the American Society of Clinical Oncology (ASCO), two of which were discussed in the «Poster Highlights Session» (SAKK 41/08 and SAKK 24/09). Data from SAKK 60/00, along with other trials, were shown in an oral presentation. At the 2014 meeting of the European Society for Medical Oncology (ESMO) there were two oral presentations (SAKK 16/00 and SAKK 17/04) and four posters concerning SAKK trials. For the SAKK 35/10 trial there was an oral presentation at the Conference of the American Society of Hematology (ASH). Further trials were presented at ELCC, ASTRO and SABCS.

New methodological standards for Phase I trials

The Statistics Department was well represented at the Conference of the International Society for Clinical Biostatistics (ISCB). There was a presentation and two posters on statistical methods. In addition, an internal working paper on randomization in Phase II trials was developed in cooperation with the Board; this was completed in 2015 and will be used as the basis for trial development. Phase I trials were also a methodological priority. Here, the traditional 3+3 design is still widely used, despite the many aspects of it that have been criticized. Alternatives were examined in cooperation with the New Anticancer Drugs project group. Further consideration will be given to this subject in 2015 too and a new SAKK standard will be established.

As well as the training course on «Investigators' Education», SAKK statisticians were also invited to give presentations at seminars in two centers: Basel and Aarau. These were well received and will be continued. If you are interested, please contact the Statistics Department at the Coordinating Center. In some cases it is still proving difficult to publish studies promptly enough for SERI and international experts, even though in many cases this can also lead to publication in higher-ranking journals. In this respect we are dependent on the cooperation of the authors and the support of the project groups. As part of our statistical advisory work, we were once more able to assist with several non-SAKK projects and contribute to publications in some cases. Again, please contact the Statistics Department if you are interested to know more. Overall, it was a good year for the department, with several publications and presentations.

Severin Strasky
Head of Fundraising &
Communications

The market environment for clinical cancer research has changed in recent years. For example, the costs of conducting clinical cancer trials have risen. In particular, the rules on patient safety and data quality have become tougher, and an increasing amount of information is required by the authorities. The administrative burden associated with more stringent regulatory requirements has led to increased costs for SAKK and the participating centers.

Growing importance of third-party funding for clinical research

The contributions defined in the service level agreement with the State Secretariat for Education, Research and Innovation (SERI) and the basic contributions from the Swiss Cancer League and Swiss Cancer Research continue to form the basis of our research activity, together with trial-specific partnerships with pharmaceutical companies. As a charitable non-profit organization, SAKK is nevertheless constantly dependent on an increase in third-party funding – especially for treatment optimization trials conducted by cooperative groups such as SAKK – in order to continue to develop independent academic research.

Exploiting synergies to the full

In order to safeguard the funding of clinical trials, heighten public awareness of the importance of clinical cancer research and strengthen recognition of the organization, the Management has decided to standardize the communication, marketing and third-party fundraising processes. The newly created Fundraising & Communications Department now supports the SAKK network on fundraising, communication and media relations matters.

2014 was a year of development and expansion: the website is increasingly becoming a communication hub, with online marketing playing a key role. In order to make the results of our research known outside the specialist communities, an editorial team was set up to identify and edit content for external communication. It was therefore possible to place research results in the daily press as well as the specialist media. SAKK also supports the exchange of knowledge and the dissemination of research results by organizing symposia (Swiss PostASCO, Orphan Malignancies Seminar).

Establishing and expanding fundraising partnerships

It was also an eventful year for fundraising. For the second time in succession, the Gateway/RT F-CCR/SAKK research prize was awarded as part of the strategic partnership with Gateway for Cancer Research and the Rising Tide Foundation for Clinical Cancer Research. The prize is worth USD 450,000 (details in the review on p. 7). Five new foundations became our partners in 2014, a vote of confidence that we very much appreciate. The SAKK 41/13 trial also won an international award – a research prize worth EUR 300,000 under the Merck Grant for Oncology Innovation scheme.

50th anniversary is an opportunity to boost awareness

Preparations for SAKK's 50th anniversary were made in 2014. In 2015, our Jubilee Year, we shall be highlighting recent successes in clinical oncology and also pursuing the goal of making our research activity better known outside specialist circles, not only in anniversary year but also beyond it, in order to strengthen the SAKK network and continue to set new treatment standards in cancer research. All in the cause of our mission: We bring progress to cancer care.

Comments on the financial reporting
In 2014, SAKK generated total revenue of CHF 12.8 million, compared with CHF 13.2 million in 2013. Operating expenses fell to CHF 4.5 million, compared with CHF 5.2 million in 2013. Owing to various delays in activating new trials and the premature closure of trials, it was not possible to achieve the budgeted revenue in the Cooperation with Industry, Cooperation with Health Insurers and Foreign Study Groups categories. Payments to the centers declined because of the low number of patients recruited.

SAKK aims to be an attractive employer
In 2014 we succeeded in making our employment conditions even more attractive. For example, the annualized working time regulations were approved and came into force on 1 January 2015. The annualized working time system offers employees significantly greater scope for organizing their working hours. This has advantages for the employer as well as for employees: Employees can align their professional activities more closely with their family commitments or individual objectives (e.g. professional development). The employer can accommodate the fluctuating workload more efficiently and thus respond to the needs of SAKK's different stakeholders. The new employment regulations were also approved. Here, too, SAKK employees benefit from attractive conditions of employment, including 10 days' paternity leave.

Continuous improvement process
The analysis of the employee survey was also a key topic in 2014. Measures to improve the working environment were put in place in the departments, and small-scale employee projects were constantly being implemented at other levels. On the reference date at the end of the year, the headcount consisted of 71 employees, including one commercial apprentice.

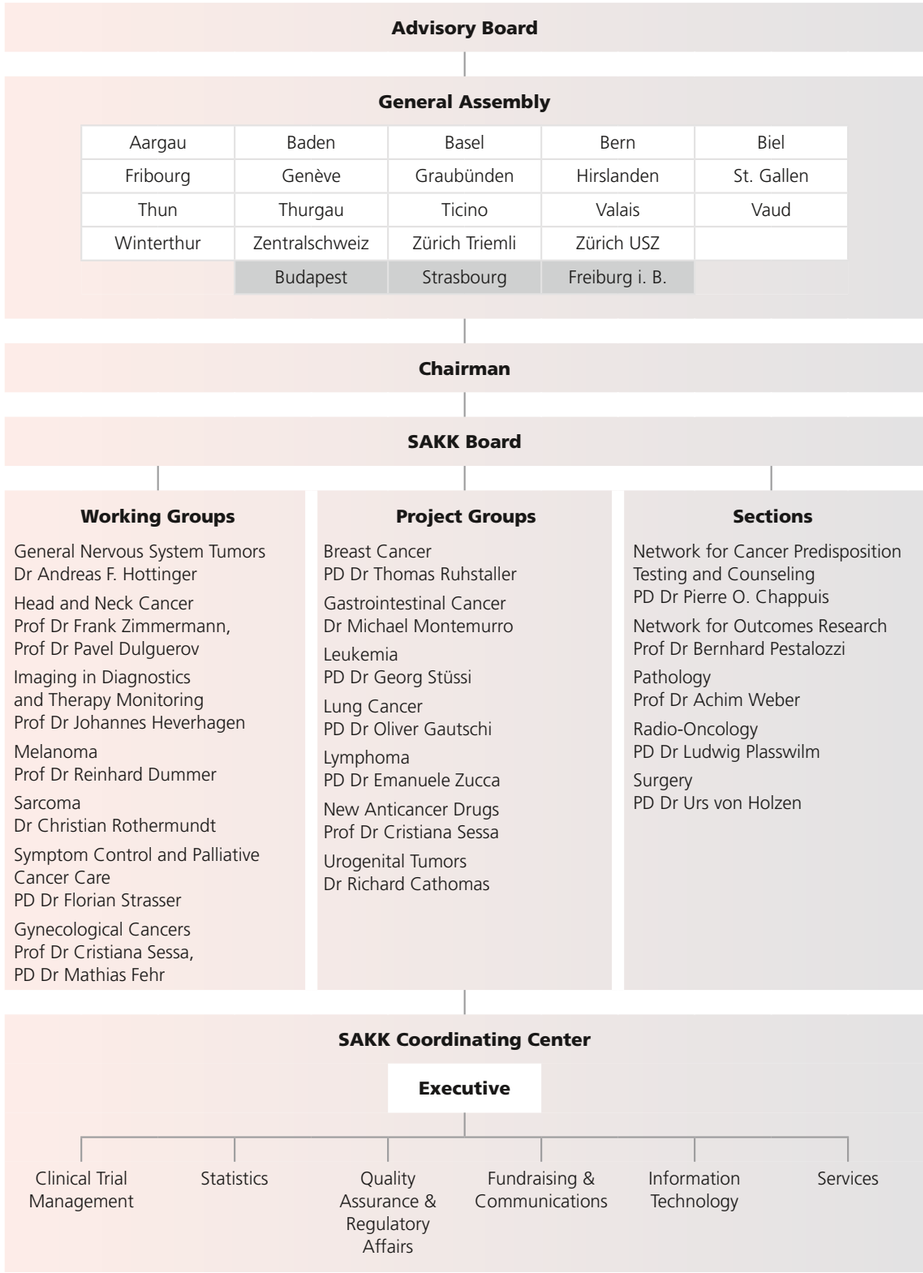
Balance sheet

As of December 31, 2014 (in CHF)	**2014**		**2013**	
Assets				
Cash and cash equivalents	6'286'815		10'809'479	
Accounts receivable	1'282'559		1'257'891	
Prepaid expenses and deferred income	731'938		861'131	
Total current assets	**8'301'311**	49.3%	**12'928'500**	71.9%
Financial assets	8'546'961		5'061'181	
Total fixed assets	**8'546'961**	50.7%	**5'061'181**	28.1%
Total assets	**16'848'272**	100.0%	**17'989'681**	100.0%
Liabilities				
Accounts payable	693'617		1'327'382	
Deferred income and accrued expenses	2'459'386		2'312'284	
Total short-term liabilities	**3'153'003**	18.7%	**3'639'666**	20.2%
Provisions for liability claims	608'156		791'156	
Total long-term liabilities	**608'156**	3.6%	**791'156**	4.4%
«Education Grant» fund	30'000		-	
«Special purpose» fund	135'963		228'063	
«Hubacher» fund	10'724'239		10'891'472	
Total special purpose fund capital	**10'890'202**	64.6%	**11'119'535**	61.8%
Organizational capital				
Free capital as at 1 January	2'344'233		2'437'333	
Group result	-147'321		-93'100	
Free capital as at 31 December	2'196'912		2'344'233	
Securities fluctuation reserve	-		95'091	
Total organizational capital	**2'196'912**	13.0%	**2'439'324**	13.6%
Total liabilities	**16'848'272**	100.0%	**17'989'681**	100.0%

Statement of operations

January 1 to December 31 (in CHF)	**2014**		**2013**	
Operating income				
Research contributions SERI[1]	5’625’750		4’760’250	
Research contributions CLS[2]	297’400		360’400	
Research contributions CRS[3]	1’011’500		1’131’300	
Research contributions SSKK[4]	100’000		100’000	
Research contributions, third parties	495’089		290’475	
Research contributions, Swiss health insurers	157’753		-67’128	
Income from industry partnerships	2’775’719		4’372’672	
Income from foreign study groups	102’253		513’443	
Income from Cancer Bulletin	306’488		319’150	
Donations, bequests, legacies	1’139’474		1’331’829	
Miscellaneous income	741’470		111’301	
Total operating income	**12’752’896**	100.0%	**13’223’692**	100.0%
Operating costs				
Miscellaneous study-related expenses	-442’525		-475’558	
Research contributions IBCSG[5]	-160’000		-250’000	
Research contributions, centres	-3’582’049		-4’153’892	
Travel, hospitality expenses	-282’303		-224’291	
Other operating expenses	-73’139		-60’537	
Total operating expenses	**-4’540’016**	-35.6%	**-5’164’279**	-39.1%
Interim result 1	**8’212’880**	64.4%	**8’059’413**	60.9%
Coordination expenses				
Personnel expenses	-7’353’414		-7’126’507	
Other coordination expenses	-1’186’027		-1’195’586	
Total coordination expenses	**-8’539’441**	-67.0%	**-8’322’094**	-62.9%
Interim result 2	**-326’561**	-2.6%	**-262’681**	-2.0%
Financial result				
Financial income	118’793		193’335	
Financial expenses	-22’554		-23’755	
Total financial result	**96’240**	0.8%	**169’580**	1.3%
Interim result 3	**-230’321**	-1.8%	**-93’100**	-0.7%
Fund changes				
Write-back of provisions	83’000		-	
Write-back of funds	-		-	
Total fund changes	**83’000**	0.7%	**-**	0.0%
Interim result 4	**-147’321**	-1.2%	**-93’100**	-0.7%
Out-of-period result				
Out-of period income				
Out-of period expenses				
Total out-of-period result relating to a different accounting period	**-**	0.0%	**-**	0.0%
Annual result	**-147’321**	-1.2%	**-93’100**	-0.7%

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



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Kantonsspital St.Gallen
(President)

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Kantonsspital Chur
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Italiana Bellinzona
(Successor of M. Ghielmini)

Prof Dr Achim Weber
Universitätsspital Zürich

The Swiss Group for Clinical Cancer Research SAKK expresses its gratitude!
In the year 2014, we were able to conduct trials in over 50 centers in Switzerland as well as in various foreign hospitals. In the past year, we have enrolled 710 cancer patients in clinical trials and in this way have been able to provide them with access to new therapy offering the best-possible option according to present scientific knowledge. Our sustained, assiduous research work is only possible thanks to the generous support of our partner organizations, corporate partners, institutional sponsors and donors. However, we must also thank those who showed their solidarity by making a bequest to SAKK. SAKK owes a debt of gratitude to all of them.

SAKK Industrypool 2014
Special thanks to the supporting pharmaceutical companies:

- Amgen Switzerland AG
- ARIAD Pharmaceuticals Inc.
- Astellas Pharma AG
- AstraZeneca AG
- Bayer (Schweiz) AG
- Boehringer Ingelheim (Schweiz) GmbH
- Bristol-Myers Squibb SA
- Celgene GmbH
- Eli Lilly (Suisse) SA
- GlaxoSmithKline AG
- Ikopharm AG
- Janssen-Cilag AG
- Lipomed AG
- MSD Merck-Sharp&Dhome AG
- Merck (Schweiz) AG
- Mundipharma Medical Company
- Novartis Pharma (Schweiz) AG
- Pfizer AG
- PharmaMar S.A.
- Pierre Fabre Pharma AG
- Roche Pharma (Schweiz) AG
- Sandoz Pharmaceuticals AG
- Sanofi-Aventis (Schweiz) AG
- Spectrum Pharmaceuticals
- Takeda Pharma AG
- Teva Pharma AG
- Vifor AG

Contributions by public authorities and third parties
- State Secretariat for Education, Research and Innovation (SERI)
- Foundation Cancer Research Switzerland
- Cancer league Switzerland
- Eugen und Elisabeth Schellenberg-Stiftung
- Gateway for Cancer Research
- Rising Tide Foundation for Clinical Cancer Research
- Swiss Foundation for Clinical Cancer Research
- Foundation Domarena
- Foundation Empiris
- Foundation for the fight against cancer
- Werner und Hedy Berger-Janser-Stiftung zur Erforschung der Krebskrankheiten
- Werner Geissberger Stiftung
- Private donors
- Bequests

Account for donations:
PC 60-2954422-0

Conducted trials 2014

Trials activated in 2014

Breast Cancers	SAKK 21/12	A Phase I and stratified, multicenter Phase II trial of trans-dermal CR1447 (4-OH-testosterone) in endocrine respon-sive-HER2 negative and triple negative-androgen receptor positive metastatic or locally advanced breast cancer
Breast Cancers	SAKK 96/12	Prevention of Symptomatic Skeletal Events with Denosumab Administered every 4 Weeks versus every 12 Weeks – A Non-Inferiority Phase III Trial
Breast Cancers	EORTC 10085 PRO	EORTC 10085 prospective part, Clinical and biological character-iza-tion of Male Breast Cancer: an international EORTC, BIG and NABCG intergroup study
Breast Cancers	IBCSG 48-14	A study evaluating the pregnancy outcomes and safety of in-ter-rupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy
Gynaecological 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
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
Leukemias	HOVON 103 - TOS	A randomized phase II multicenter study with a safety run-in to assess the tolerability and efficacy of the addition of oral tosedostat to standard induction chemotherapy in AML and high risk myelod-ysplasia (MDS) (IPSS-R > 4.5) in patients aged ≥ 66
Lung Cancers	SAKK 15/12	Early prophylactic cranial irradiation with hippocampal avoid-ance in patients with limited disease small-cell lung cancer. A multicenter phase II trial
Lymphomas	SAKK 39/13	Nelfinavir as Bortezomib-sensitizing drug in patients with proteasome inhibitor-nonresponsive myeloma
New Drugs	SAKK 21/12	A Phase I and stratified, multicenter Phase II trial of trans-dermal CR1447 (4-OH-testosterone) in endocrine respon-sive-HER2 negative and triple negative-androgen receptor positive metastatic or locally advanced breast cancer
New Drugs	SAKK 69/13	Phase IB of oral BGJ398 (pan FGFR inhibitor) and oral BYL719 (a specific PI3K inhibitor) in adult patients with se-lected solid tumors
Urogenital Cancers	SAKK 63/12	Prospective cohort study with collection of clinical data and serum of patients with prostate disease
Urogenital Cancers	SAKK 96/12	Prevention of Symptomatic Skeletal Events with Denosumab Administered every 4 Weeks versus every 12 Weeks – A Non-Inferiority Phase III Trial

Trials open for accrual in 2014

Breast Cancers	SAKK 21/12	A Phase I and 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
Breast Cancers	SAKK 22/10	A randomized phase II trial of pertuzumab in combination with trastuzumab with or without chemotherapy, both followed by T-DM1 in case of progression, in patients with HER2-positive metastatic breast cancer
Breast Cancers	SAKK 26/10	Impact of Recurrence Score® on Recommendations for Adjuvant Treatment in Patients with ER-positive Breast Cancer
Breast Cancers	SAKK 28/12	Standardization project for Ki-67 assessment in G2 breast cancer A retrospective study
Breast Cancers	SAKK 96/12	Prevention of Symptomatic Skeletal Events with Denosumab Administered every 4 Weeks versus every 12 Weeks – A Non-Inferi-ority Phase III Trial
Breast Cancers	EORTC 10085 PRO	EORTC 10085 prospective part, Clinical and biological characteriza-tion of Male Breast Cancer: an international EORTC, BIG and NABCG intergroup study
Breast Cancers	IBCSG 48-14	A study evaluating the pregnancy outcomes and safety of interrupt-ing endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy
Breast Cancers	IBCSG 38-10	A randomized phase III study of radiation doses and fractionation schedules for ductal carcinoma in situ (DCIS)
Gastrointestinal Cancers	SAKK 40/04	Clinical function after total mesorectal excision and rectal replace-ment. A prospective randomized trial comparing side-to-end anastomosis, colon-J-pouch and straight coloanal anastomosis
Gastrointestinal Cancers	SAKK 41/10	Cetuximab Monotherapy versus Cetuximab plus Capecitabine as first-line treatment in elderly patients with KRAS wild-type me-ta-static colorectal cancer
Gastrointestinal Cancers	SAKK 77/09	A phase I open label/phase II randomized, double-blind, multicenter trial investigating the combination of everolimus and TransArterial ChemoEmbolisation (TACE) with doxorubicin in patients with hepatocellular carcinoma eligible for TACE
Gynaecological 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
Gynaecological cancers	Mito/Mango 16b	A multicenter phase III randomized study with second line chemo-therapy plus or minus bevacizumab in patients with platinum sensitive epithelial ovarian cancer recurrence after a bevacizumab/ chemotherapy first line
Leukemias	APL 2006	Randomized phase III trial assessing the role of arsenic trioxide and/ or ATRA during consolidation course in newly diagnosed acute promyelocytic leukemia (APL)

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
Leukemias	EBMT HCT vs CT	Compare conventinal chemotherapy to low dose total body irradiation-based conditioning and hematopoietic cell transplan-ta-tion as consolidation therapy
Leukemias	GRAALL 2005	Protocole multicentrique de traitement des leucémies aiguës lymphoblastiques (LAL) de l'adulte jeune (18-59 ans)
Leukemias	HOVON 103 - LEN	Randomized multicenter phase II trial with a safet y run-in to assess the tolerability and efficacy of the addition of new drugs to standard induction chemotherapy in AML and RAEB ≥ 66 years
Leukemias	HOVON 103 - TOS	A randomized phase II multicenter study with a safety run-in to assess the tolerability and efficacy of the addition of oral tosedostat to standard induction chemotherapy in AML and high risk myelod-ysplasia (MDS) (IPSS-R > 4.5) in patients aged ≥ 66
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
Lung Cancers	SAKK 16/08	Preoperative chemotherapy and radiotherapy with concomitant Cetuximab in non-small cell lung cancer (NSCLC) patients with IIIB disease. A multicenter phase II trial
Lung Cancers	SAKK 19/09	Bevacizumab, pemetrexed and cisplatin, or erlotinib and bevacizum-ab for advanced non-squamous NSCLC stratified by EGFR mutation status. A multicenter phase II trial including biopsy at progression (BIO-PRO trial)
Lung Cancers	BELIEF	A phase II trial of erlotinib and bevacizumab in patients with advanced non-small cell lung cancer and activating EGFR mutations. Bevacizumab and ErLotinib In EGFR mut + NSCLC. A clinical trial of ETOP
Lung Cancers	EMPHASIS	A randomized phase III trial of erlotinib versus docetaxel in patients with advanced squamous cell non-small cell lung cancer who failed first line platinum based doublet chemotherapy stratified by VeriStrat Good vs VeriStrat Poor
Lymphomas	SAKK 38/08	Rituximab, bendamustine and lenalidomide in patients with aggressive B-cell lymphoma not eligible for high dose chemo-therapy or anthracycline-based therapy. A phase I/II trial
Lymphomas	SAKK 39/10	Nelfinavir and lenalidomide/dexamethasone in patients with progressive multiple myeloma that have failed lenalidomide-containing therapy. A single arm phase I/II trial
Lymphomas	SAKK 39/13	Nelfinavir as Bortezomib-sensitizing drug in patients with proteasome inhibitor-nonresponsive myeloma
Lymphomas	EMN-02 Hovon 95	Randomized phase III trial to compare Bortezomib, Melphalan, Pred-nisone (VMP) with High Dose Melphalan followed by Bortezomib, Lenalidomide, Dexamethasone (VRD) consolidation and Lenalidomide maintenance in patients with newly diagnosed multiple myeloma
Lymphomas	HD 16	HD16 for early stages: Treatment optimization trial in the first-line treatment of early stage Hodgkin lymphoma; treatment stratifica-tion by means of FDG-PET
Lymphomas	HD 17	Therapieoptimierungsstudie in der Primärtherapie des intermediären Hodgkin Lymphoms: Therapiestratifizierung mittels FDG-PET
Lymphomas	HD 18	Therapieoptimierungsstudie in der Primärtherapie des fortgeschrit-tenen Hodgkin Lymphoms: Therapiestratifizierung mittels FDG-PET
Lymphomas	IELSG-32	Randomized Phase II trial on primary chemotherapy with high-dose methotrexate and high-dose cytarabine with or without thiotepa, and with or without rituximab, followed by brain irradiation vs. high-dose chemotherapy supported by autologous stem cells transplantation for immunocompetent patients with newly diagnosed primary CNS lymphoma
Lymphomas	IELSG-37	A randomized, open-label, multicentre, two-arm phase III compara-tive 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)
Lymphomas	REMoDL-B	A randomised evaluation of Molecular guided therapy for Diffuse Large B-Cell Lymphoma with Bortezomib (phase III)
Lymphomas	T-Cell Project	Das T-Cell project ist eine Registrierstudie mit Referenzpathologie um Daten zu seltenen malignen Erkrankungen der T-Zell Linie zu gewinnen. Nachträgliche Erfassung im PATRAS am 06.09.2013, Freigabe ca. 2008/2009
New Drugs	SAKK 21/12	A Phase I and 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
New Drugs	SAKK 65/12	Phase I study of LDE225 in combination with Paclitaxel in patients with advanced solid tumors
New Drugs	SAKK 66/12	A Phase I, open-label, multi-center, dose escalation study of oral CGM097, a p53/HDM2-interaction inhibitor, in adult patients with selected advanced solid tumors characterized by wild-type TP53
New Drugs	SAKK 66/13	INC280 Combination with BKM120 for glioblastoma patients, Phase I/II trial
New Drugs	SAKK 67/13	Phase I study of oral PQR309 in Patients with Advanced Solid Tumors
New Drugs	SAKK 69/13	Phase IB of oral BGJ398 (pan FGFR inhibitor) and oral BYL719 (a specific PI3K inhibitor) in adult patients with selected solid tumors
Urogenital Cancers	SAKK 08/11	Orteronel maintenance therapy in patients with metastatic castration resistant prostate cancer and non-progressive disease after first-line docetaxel therapy: a multicenter randomized double-blind placebo-controlled phase III trial
Urogenital Cancers	SAKK 09/10	Dose intensified salvage radiotherapy in biochemically relapsed prostate cancer without macroscopic disease. A randomized phase III trial
Urogenital Cancers	SAKK 01/10	Carboplatin Chemotherapy and Involved Node Radiotherapy in Stage IIA/B Seminoma
Urogenital Cancers	SAKK 63/12	Prospective cohort study with collection of clinical data and serum of patients with prostate disease
Urogenital Cancers	SAKK 96/12	Prevention of Symptomatic Skeletal Events with Denosumab Administered every 4 Weeks versus every 12 Weeks – A Non-Inferi-ority Phase III Trial
Urogenital Cancers	STAMPEDE	Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy A multi-arm multi-stage randomised controlled trial

Trials closed for accrual in 2014

Breast Cancers	SAKK 26/10	Impact of Recurrence Score® on Recommendations for Adjuvant Treatment in Patients with ER-positive Breast Cancer
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Urogenital Cancers	SAKK 09/10	Dose intensified salvage radiotherapy in biochemically relapsed prostate cancer without macroscopic disease. A randomized phase III trial

Accrual numbers per disease and member

New Drugs	Gynaecological Cancers	Gastrointestinal Cancers	Lymphomas	Leukemias	Breast Cancers	Lung Cancers	Urogenital Cancers	**Totals**		
47	**14**	**21**	**122**	**26**	**296**	**55**	**140**	**710**		
0	2	2	10	4	9	0	3	**30**	**Aargau**	**Aarau Kantonsspital** **Olten Kantonsspital**
0	0	1	4	0	2	1	1	**9**	**Baden**	**Kantonsspital**
6	1	1	13	2	25	2	15	**65**	**Basel**	**Universitätsspital** **Liestal Kantonsspital**
2	0	4	15	4	20	0	4	**47**	**Bern**	**Inselspital** **Oncocare Sonnenhof-Klinik Engeried** **Engeriedspital**
0	0	1	0	0	9	1	7	**18**	**Biel**	**Spitalzentrum AG**
0	0	2	2	0	10	4	0	**18**	**Fribourg**	**Hôpital Fribourgeois**
0	0	0	0	7	1	2	0	**10**	**Genève**	**Hôpital Universitaire Genève**
10	1	2	8	0	22	4	27	**72**	**Graubünden**	**Chur Kantonsspital**
0	0	0	6	0	33	0	2	**41**	**Hirslanden**	**Zürich Hirslandenklinik** **Brustzentrum Zürich Seefeld** **Aarau Hirslandenklinik**
10	2	1	22	2	30	5	18	**85**	**St. Gallen**	**Kantonsspital** **ZeTuP**
0	0	0	5	0	6	5	0	**16**	**Thun**	**Spital STS AG** **Radio-Onkologie Berner Oberland**
0	2	0	0	0	5	0	2	**9**	**Thurgau**	**Frauenfeld Kantonsspital** **Münsterlingen Kantonsspital**
8	5	1	8	2	14	5	6	**47**	**Ticino**	**IOSI** **Varini&Calderoni Oncology** **Fondazione Oncologia**
0	0	1	4	0	8	0	6	**19**	**Valais**	**Sion CHCVS** **Brig SZO**
1	0	0	0	2	3	9	3	**18**	**Vaud**	**Lausanne CHUV**
0	0	1	4	0	16	4	6	**31**	**Winterthur**	**Kantonsspital**
0	1	1	5	2	13	6	2	**30**	**Zentralschweiz**	**Luzern Kantonsspital**
0	0	2	5	0	2	0	1	**10**	**Zürich Triemli**	**Zürich Triemli**
1	0	1	11	1	12	7	0	**33**	**Zürich USZ**	**Zürich Universitätsspital**
9	0	0	0	0	56	0	37	**102**	**Foreign Countries**	

Publications of SAKK and cooperative groups 2014

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Urogenital Cancers

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Lung Cancers

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Breast Cancers

SAKK 92/08

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Presentations of SAKK-trials (without cooperative groups)

ASCO Annual Meeting 2014

Oral presentation

Sargent DJ. et al. Prognostic impact of deficient mismatch repair (dMMR) in 7,803 stage II/III colon cancer (CC) patients (pts): A pooled individual pt data analysis of 17 adjuvant trials in the ACCENT database (SAKK 60/00).

Poster discussion

Von Moos R. et al. Neoadjuvant radiotherapy (RT) combined with capecitabine (Cape) and sorafenib (Sor) in patients (pts) with locally advanced, k-ras-mutated rectal cancer (LARC): A phase I/II trial SAKK 41/08.

Rochlitz C. et al. SAKK 24/09: Safety and tolerability of bevacizumab plus Paclitaxel vs. bevacizumab plus metronomic cyclophosphamide and capecitabine as first-line therapy in patients with HER2-negative advanced stage breast cancer. A multicenter, randomized phase III trial.

Poster

Templeton A. et al. Prevention of symptomatic skeletal events with denosumab administered every 4 weeks versus every 12 weeks – a non-inferiority phase III trial (SAKK 96/12, REDUSE).

Koeberle D. et al. Sorafenib with or without everolimus in patients with unresectable hepatocellular carcinoma (HCC): A randomized multicenter phase II trial (SAKK 77/08 and SASL 29).

ELCC 2014 European Lung Cancer Conference Geneva

Poster

Gautschi O. et al. Thymidylate synthetase (TYMS) expression is not predictive in patients with metastatic NSCLC treated with pemetrexed, cisplatin and bevacizumab in the SAKK19/09 trial.

35th Annual Conference of the International Society for Clinical Biostatistics

Oral presentation

Mayer M. et al. Quantile Regression and Prediction Intervals for Survival Data.

Poster

Hayoz S. et al. Effect of one-patient clusters on power in cluster-randomized trials.

Bigler M. Comparison of design options for phase IB clinical trials in oncology: simulation results.

ESMO 2014 congress Madrid

Oral presentations

Pless M.et al. Final results of the SAKK 16/00 trial: a randomized phase III trial comparing neoadjuvant chemoradiation to chemotherapy alone in stage IIIA/N2 nonsmall cell lung cancer (NSCLC).

Stahel RA. et al. Neoadjuvant chemotherapy and extrapleural pneumonectomy of malignant pleural mesothelioma (MPM) with or without hemithoracic radiotherapy: final results of the randomized multicenter phase II trial SAKK17/04.

Poster discussion

Montemurro M.et al. Long-term outcome of dasatinib first-line treatment in gastrointestinal stromal tumors: A multicenter two stage phase II trial SAKK 56/07.

Poster

Templeton A. et al. Prevention of symptomatic skeletal events with denosumab administered every 4 weeks versus every 12 weeks-a non-inferiority phase III trial: SAKK 96/12 - REDUSE.

Rothschild S. et al. Prospective evaluation of circulating VEGF in patients with advanced nonsmall cell lung cancer treated with bevacizumab, pemetrexed and cisplatin in the trial SAKK19/09.

Matter-Walstra K. et al. Health economic analysis of the randomized multicenter phase II trial SAKK 77/08: sorafenib with or without everolimus in patients with unresectable hepatocellular carcinoma (HCC).

ASTRO 56th Annual Meeting

Poster

Ghadjar P. et al. Impact of weight loss on survival after chemoradiation for locally advanced head and neck cancer. Secondary results of a randomized phase III trial (SAKK 10/94).

San Antonio Breast Cancer Symposium

Poster

O. Pagani et. al. Advanced HER2 positive breast cancer treated with trastuzumab: is combination with chemotherapy always needed? Randomized Phase III trial SAKK 22/99.

K. Matter-Walstra et al. Health economic evaluation of the SAKK Trial 24/09: Safety and tolerability of bevacizumab plus paclitaxel vs. bevacizumab plus metronomic cyclophosphamide and capecitabine as first-line therapy in patients with HER2-negative advanced stage breast cancer. A multicenter, randomized phase III trial.

56th ASH Annual Meeting San Francisco

Oral presentation

E. Kimby et al. Rituximab plus lenalidomide improves the complete remission rate in comparison with rituximab monotherapy in untreated follicular lymphoma patients in need of therapy. Primary endpoint analysis of the randomized phase-2 trial SAKK 35/10.

Poster

C. Driessen et al. SAKK 65/08: A Phase I Dose Escalation Study of Bortezomib in Combination with Nelfinavir in Patients with Advanced Hematologic Malignancies.

Fleury I. et al. No Increased Risk of Secondary Neoplasms in Patients Treated with Rituximab for Non-Hodgkin's Lymphoma: A Meta-Analysis of 9 Trials (SAKK 35/98).

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