

# Annual Report 2022





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# We are in excellent shape



“ We are confident that cancer research in SAKK’s academic research network in Switzerland offers the best possible conditions. For patients and researchers alike.

**Prof. Dr. med. Miklos Pless** President

2022 was a year of fresh beginnings at SAKK. With financial and organizational restructuring complete, SAKK focused on consolidating member trust on the one hand, and on implementing the new organizational structures on the other. The years ahead will bring additional challenges, but SAKK's new structure means it is in excellent shape to deal with them. Board President Prof. Dr. med. Miklos Pless is confident that this is the case.

Not only are cancer treatments becoming ever more personalized and successful, they are also becoming more complex, interdisciplinary and professional. We are convinced that a cooperative research group is the only way forward for clinical cancer research in Switzerland and a concept that promises success. Only a robust network is capable of managing sustainable, modern academic cancer research. SAKK has a network of this kind. Our goal must be to ensure that all patients in Switzerland have access to good clinical trials, regardless of where they live, their social status or the type of cancer they have.

The years ahead will present Switzerland with a wide range of challenges, one of which is the growing number of elderly people with multiple morbidities. Moreover, this trend is emerging at a time when staff are in short supply and financial resources are stagnating. Promoting up-and-coming academic talent is one way of meeting these challenges. Digitalization and decentralized trials are a source of further potential solutions. In any case, SAKK will rise to these challenges. And it will do more than that since it has set itself the goal of being a pioneer in Switzerland's research landscape.

SAKK intends to significantly increase the number of active trials during 2023, thus giving more patients access to innovative treatments. This will take place in close consultation with the SAKK Patient Advisory Board, so that we can take better account of patients' needs. We will continue to focus on conducting good registries. In collaboration with Swissmedic, SAKK also intends to initiate a pilot decentralized clinical trial. This will mark a major step forward in the future of clinical research.

We are confident that cancer research in SAKK's academic research network in Switzerland offers the best possible conditions. For patients and researchers alike.

Finally, I would like to thank everyone for their commitment: the team in our Competence Center, our members in hospitals, and all researchers in the project groups, working groups and sections. However, I would also like to extend my gratitude to our patients, who place their trust in the treatment we provide. We have an academic and moral obligation to honor this trust and to do our best to improve the lot of people living with cancer in Switzerland.



# We're on course



” SAKK achieves success when it brings the right people together, and works with them to create an ideal environment for effective cancer research.

**Dr. Hans Rudolf Keller** Chief Executive Officer

In 2022, SAKK created a framework for professionalizing and stabilizing its organization. In doing so, it took a major step toward achieving its goal. A discussion on 2022 with CEO Dr. Hans Rudolf Keller.

**Dr. Keller, what was 2022 like for you?**

**Hans Rudolf Keller:** Since it was my first year at SAKK, I'm particularly pleased to say that we made a lot of progress. We completely revamped our management. We restructured our governing and operational bodies. We also totally revised our organizational and business rules and conflict of interest policy. Our new organization reflects the purpose of SAKK and takes on board the rules of responsible corporate management. As a result, we can say that we're on course. At all levels. We're also on a sound financial footing.

**How did the members and partners respond to these changes?**

**Hans Rudolf Keller:** We held extensive discussions with them—with the majority of members, with industry partners, with the Swiss Cancer League, the Swiss Cancer Research Foundation, Oncosuisse, the Swiss Clinical Trial Organisation and many more. We are very grateful for their trust. The support of the State Secretariat for Education, Research and Innovation is also extremely valuable. In the course of our discussions, we even managed to recruit a new member in the form of Réseau hospitalier neuchâtelois. That takes the total number of SAKK members to 22.

**What happened during 2022 in terms of research?**

**Hans Rudolf Keller:** We fulfilled our mandate and made gratifying progress. We successfully completed and published several trials, such as SAKK 01/10 on testicular cancer and the international POSITIVE trial, to which SAKK made an important contribution. 30 trials were open for patient accrual, and we still have capacity. That's why we launched the Network Trial Award, the first call for proposals of SAKK's own. The competition, which has prize money of CHF 1 million, invites proposals from doctors in the SAKK network.

**What's on the horizon for 2023?**

**Hans Rudolf Keller:** SAKK achieves success when it brings the right people together, and works with them to create an ideal environment for effective cancer research. In 2023, we will therefore continue to drive forward trust-based collaboration with oncologists in our network and with partners from industry and other organizations. We will complete one major trial and launch new trials. By doing so we will strengthen our reputation for expert clinical cancer research. Among all stakeholders.



# SAKK in Figures



## Our network

1

network

made up of 22 regular members, 3 associate members, 8 phase I sites, 16 research partners, 36 industry partners, 17 authorities and foundations, 8 partner organizations

20

specialized bodies

working in project groups, working groups and sections

80

employees

working in the Group's Competence Center

7

Patient Advisory Board members

contributing the perspective of people living with cancer to our strategy, communications, trial development and trial conduct

## Our work

30

open clinical trials

researching effective and well tolerated new cancer therapies and better treatments

576

patients

we would like to thank for participating in our trials in 2022

34

scientific articles

published by oncologists and hematologists in scientific journals

## Our support activities

5

awards

were presented to researchers by us in conjunction with our industry partners

9

mentees

of the Young Oncology Academy took part in SAKK's support and mentoring program

# Every contribution is valuable



“ Every contribution helps us conduct further trials to combat cancer. Our sincere gratitude to everyone who already supports us.

**Jürg Tschofen** Chief Financial Officer

Clinical cancer research is both a necessary and challenging activity. One major challenge during 2022 was familiarization and the associated task of placing all marketing and communication activities on a new footing and obtaining feedback from outside SAKK. Nevertheless, it was a successful year in financial as well as other respects. A discussion with CFO Jürg Tschofen.

**Mr. Tschofen, what motivates you in your work for SAKK?**

**Jürg Tschofen:** Figures are an important part of successfully gearing our organization to patients and all other stakeholders. What's most important to me though is that we are driven by emotional power. We would like to encourage collaboration with our donors. To do this, we are seeking dialog so that we can take wishes, particular concerns, or restrictions seriously, with donors as much as with foundations or people who leave us money in their wills.

**With what aim?**

**Jürg Tschofen:** We do not see our impact as being ultimately restricted to clinical cancer research. We also see it as a resource for alleviating and avoiding disease. On the one hand, this affects patients and their relatives, but it also affects everyone involved in treatment and nursing, from initial diagnosis through to cure or prevention. To achieve this goal, we are endeavoring to amalgamate research in the oncology environment, to the best of our knowledge and belief and guided by the latest science. By doing so, we encourage synergies and create advantages. Our work covers all cancer types and the whole of Switzerland.

**That's a cost-intensive commitment.**

**Jürg Tschofen:** We are constantly reliant on extra funding to contain the expected spread in disease types. The vast majority of financial resources that our organization receives go into clinical research, and not only because research is our organization's primary area of activity. We minimize advertising expenditure in the interests of our patients. As a result, we can be confident that the donations we receive help drive clinical cancer research rather than just being frittered away on administration or expensive advertising campaigns. That makes us unique in Switzerland.

**So every donation is an investment in the future?**

**Jürg Tschofen:** Cancer is an insidious disease. We all carry its seeds, and it can break out at any time. As a society, we are increasingly exposed to it. That's why driving forward cancer cures is one of our top priorities. We are always pleased when we can recruit people to become part of our team. Every contribution helps us conduct further trials to combat cancer. We offer our sincere gratitude to everyone who already supports us, on our own behalf and on behalf of the countless patients who have placed their trust in us over the years, as well as those who will do so in the future.

# Thank you for your support

## Public sector and third parties

Alfred und Anneliese Sutter-Stöttner Stiftung  
Fondazione Epatocentro Ticino  
Fondazione Istituto di Ricerche Farmacologiche  
Mario Negri (Suisse)  
Insel Gruppe AG  
Klinikum der Universität München  
Kurt und Senta Herrmann-Stiftung  
Norges teknisk-naturvitenskapelige universitet NTNU  
Notariat Martin Stauffer  
Rising Tide Foundation for Clinical Cancer Research  
santésuisse  
SOHC Board of Trustees  
SPS Foundation  
State Secretariat for Education, Research  
and Innovation SERI  
Stiftung zur Krebsbekämpfung  
Swiss Cancer Foundation  
Swiss Cancer League  
Swiss Cancer Research Foundation  
Swiss Foundation for Clinical Cancer Research SSKK  
Swiss Paediatric Oncology Group SPOG

## Industry

AbbVie AG  
Advanced Accelerator Applications International SA  
AGO Research GmbH  
Amgen Switzerland AG  
Astellas Pharma AG  
Astellas Pharma Europe Ltd.  
AstraZeneca AG  
Basilea Pharmaceutica International AG

Bayer (Schweiz) AG  
Bayer Healthcare Pharmaceutical, Pittsburgh, USA  
Bayer HealthCare Pharmaceuticals Inc., New Jersey, USA  
BeiGene Switzerland GmbH  
Boehringer Ingelheim (Schweiz) GmbH  
Bristol-Myers Squibb SA, Steinhausen, Switzerland  
Bristol-Myers Squibb SA, Chester, United Kingdom  
Celgene GmbH (Switzerland)  
Clovis Oncology Switzerland GmbH  
Daiichi Sankyo (Schweiz) AG  
Eli Lilly (Suisse) SA  
Exact Sciences International GmbH  
F. Hoffmann-La Roche Ltd  
Fédération Francophone de  
Cancérologie Digestive FFCD  
Gilead Sciences Switzerland Sàrl  
GlaxoSmithKline AG  
IDEOGEN AG  
Immunophotonics Inc.  
Incyte Biosciences International Sàrl  
InnoMedica Schweiz AG  
Intensity Therapeutics  
IPSEN Pharma Schweiz GmbH  
IQONE HEALTHCARE SWITZERLAND SA  
Janssen Pharmaceutica NV  
Janssen-Cilag AG  
MaxiVAX SA  
Merck (Schweiz) AG  
MSD Merck Sharp & Dohme AG  
Myriad Genetics GmbH  
Myriad Service GmbH  
Novartis Pharma Schweiz AG

Pfizer AG  
Pharma Mar S.A.  
Pierre Fabre Pharma AG  
Sanofi-Aventis (Schweiz) AG  
Seagen International GmbH  
Takeda Pharma AG  
Vivesto AB  
Zentiva c/o Helvepharm AG

## International research groups

Deutsche CLL Studiengruppe DCLLSG  
ETOP IBCSG Partners Foundation  
European Organisation for Research and Treatment  
of Cancer (AISBL/IVZW) EORTC  
GHSG Studienzentrale  
HOVON Stichting  
International Breast Cancer Study Group IBCSG

## Additional donations from our members

Cantonal Hospital Baden AG  
Cantonal Hospital Graubünden  
Cantonal Hospital St.Gallen  
Forschungsstiftung Hirslanden  
Insel Gruppe AG  
Lausanne University Hospital (CHUV)  
St. Clara Forschung AG  
University Hospital Basel  
University Hospital Zurich

# Promoting dialog

Treating cancer requires knowledge and experience. SAKK promotes collaboration and the development of effective cancer treatments in many different ways. Training courses, events, forums and symposia help open up fresh perspectives on the treatment of cancer patients.

In 2022, participants at meetings held in parallel to international congresses such as ESMO, AACR and ASH were able to discuss new paths in cancer research with acknowledged experts. Introductory courses in Lausanne and St.Gallen taught doctors, geneticists, nurses and other members of the healthcare professions more about genetic counseling in oncology. Finally, at its semi-annual meeting in November, SAKK once again joined with industry and research partners to present five awards to established and upcoming researchers.

January 8, 2022  
**GU Cancer Forum**  
Zurich

January 27, 2022  
**GU Cancer Forum**  
Lausanne

January 27, 2022  
**SAKK Training Course  
for CRCs and CTNs**  
Bern

March 10–17, 2022  
**SAKK Investigators' Education**  
Bern

April 19, 2022  
**GU Cancer Forum**  
Lugano

May 5, 2022  
**2<sup>nd</sup> Swiss PostAACR**  
Zurich

May 5–6, 2022  
**SAKK Semi-Annual Meeting**  
Zurich

June 8–11, 2022  
**Chicago in the Mountains**  
Flüeli-Ranft

June 23, 2022  
**16<sup>th</sup> Swiss PostASCO**  
Bern

June 24–25, 2022  
**10<sup>th</sup> Introductory Course  
in Genetic Counseling  
in Oncology**  
St.Gallen

August 25, 2022  
**SAKK Training Course  
for CRCs and CTNs**  
Bern

August 29, 2022  
**Industry Pool Meeting**  
Bern

September 2–3, 2022  
**11<sup>th</sup> Introductory Course  
in Genetic Counseling  
in Oncology**  
Lausanne

September 14–16, 2022  
**ESMO in the Alps**  
Zurich

September 22–23, 2022  
**Translational Urogenital  
Cancer Network Meeting**  
Zurich

September 29, 2022  
**SAKK Online secuTrial®  
Training Course for CRCs  
and CTNs**  
Online

November 16–18, 2022  
**SOHC / SAKK Semi-Annual  
Meeting**  
Basel

November 18, 2022  
**SAKK Patient Forum  
"Quality of Life and Cancer"**  
Basel

November 24, 2022  
**Post-APCCC 2022**  
Bern

December 15–16, 2022  
**3<sup>rd</sup> SAKK SMASH**  
Dübendorf



# Our Board



“ Cancer can affect anyone— Improving and extending the lives of everyone with the disease is what motivates all of us working in clinical cancer research.

**Prof. Dr. med. Dr. phil. nat. Sacha Rothschild**

“ Every single person with cancer in Switzerland should be given a chance of even better treatment and prognosis. That’s what SAKK is all about.

**Prof. Dr. med. Miklos Pless** President

“ SAKK gives everyone with cancer in Switzerland access to medical progress. I want to help make sure that remains the case.

**PD Dr. med. Richard Cathomas**

“ Cancer and cancer research are among the biggest inter-professional challenges of the future. That’s why I enjoy contributing to SAKK as a health economist.

**Dr. oec. HSG Willy Oggier**

“ Working together for efficient research and findings and the best therapy.

**Marianne Binder-Keller**

“ I see my role as optimizing university hospitals’ involvement in SAKK.

**Prof. Dr. med. Urban Novak**

# Our Patient Advisory Board

SAKK began involving patients at an early stage, setting up its Patient Advisory Board in 2015. In 2022, the Advisory Board showed great commitment in helping SAKK communicate research results.

Patient and public involvement—PPI for short—describes the process of actively involving patients in the planning and implementation of new research projects. PPI activities are constantly increasing throughout Switzerland, and they have growing relevance for researchers.

SAKK began involving patients in its processes at an early stage, setting up its Patient Advisory Board back in 2015. As an advisory body it is now firmly embedded in the SAKK organization. Its members contribute the perspective of people living with cancer to SAKK's strategy, communications, trial development and trial conduct. Research groups are interested in its perspectives, while sponsors even demand its involvement in some cases.

In 2022, the Patient Advisory Board again made a valuable contribution to SAKK's success. With the aid of the Rising Tide Foundation for Clinical Cancer Research, it developed lay summaries for three SAKK trials and organized several series of public lectures on the subject of quality of life and cancer. It also reviewed the patient information for a trial being run by an external company and assessed three trial proposals from a patient perspective.

This is a remarkable example of how collaboration at all levels promotes the success of effective cancer therapies.





# Trial SAKK 01/10



” In the past 15 years, I have progressed professionally, assumed new clinical responsibilities and pursued additional projects. The trials involving SAKK have shaped my career.

**Dr. med. Alexandros Papachristofilou** University Hospital Basel



Dr. med. Alexandros Papachristofilou is senior physician in radio-oncology at University Hospital Basel and vice president of the SAKK Project Group Urogenital Tumors. The trial he launched with SAKK on testicular tumors with limited metastasis in the abdominal or pelvic lymph nodes is opening up new approaches in the treatment of testicular cancer.

**Dr. Papachristofilou, how did you get involved with SAKK?**

**Alexandros Papachristofilou:** I first came into contact with SAKK 15 years ago. I had just arrived in Switzerland, young and full of motivation, you could say. The SAKK network was new to me. All the same, my boss suggested I go to the urogenital tumors meeting to represent our clinical unit. I was just a third-year junior doctor at the time. I found it really exciting that oncologists, radio-oncologists, surgeons and pathologists sat together and debated ideas for trials.

**What fascinated you about testicular tumors?**

**Alexandros Papachristofilou:** Treating testicular tumors is definitely not one of the core activities of most doctors working in oncology, but the more I read about how they are treated, the more I was perturbed by the fact that the treatments we use are pretty toxic. So I started wondering if we shouldn't use "smaller-scale" radiotherapy but add a "little" chemotherapy instead? Or in other words, aren't two different but weaker treatments better than one type of full-on treatment? My inspiration came from the treatment used for Hodgkin lymphoma. We've been using the same approach there for nearly 50 years and it works really well.

**How did your colleagues respond to your idea?**

**Alexandros Papachristofilou:** They thought it was really interesting, but felt Switzerland was much too small to test it out. They said I should go up to Hamburg: "You need to sell your idea to the Germans", Prof. Dr. med. Silke Gillessen told me. "Things will only happen if you get them on board". The members of the German Cancer Society's Testicular Cancer Study Group had never done a trial with SAKK, but everything they had heard about SAKK had been positive. So I approached the SAKK Board with a trial proposal, which was promptly turned down. At the time, I felt very disappointed. But after it had been revised several times and I gave a face-to-face presentation to the SAKK Board, the project was finally approved. This was about 18 months after the trial had

first been drafted. We were able to secure a grant from the Rising Tide Foundation for Clinical Cancer Research to fund the trial.

**How did the trial go?**

**Alexandros Papachristofilou:** In just under six years, we accrued 120 patients at 20 trial sites. That makes SAKK 01/10 the biggest trial to have ever been conducted in stage II seminoma. We presented our results at the 2021 ESMO Congress and published them in *The Lancet Oncology* in fall 2022. The therapeutic regimen we tested is now a possible new standard of care. We're trying to further improve the treatment in our follow-on trial, SAKK 01/18.

**And your conclusions?**

**Alexandros Papachristofilou:** In the past 15 years, I have progressed professionally, assumed new clinical responsibilities and pursued additional projects. The trials involving SAKK have shaped my career. It's not always been easy, but I've got to know and work with a lot of people who have always supported me, both at the SAKK Competence Center and in the SAKK network. Would I do it again? Absolutely.

# Young Oncology Academy

The Young Oncology Academy, or YOA for short, is at the heart of SAKK's efforts to promote upcoming scientists. The promotion and mentoring program is intended for junior doctors in oncology.

Participants are mentored by a respected faculty member for a period of almost one year. During this time, the talented young doctors learn how to successfully develop, lead, conduct and publish a clinical trial. Academy members also attend congresses such as those organized by the European Society for Medical Oncology, the European Hematology Association or the European Society for Radiotherapy and Oncology.

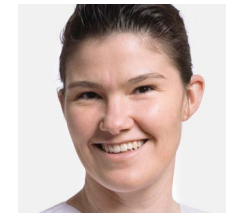
## More information at:

<https://www.sakk.ch/en/young-oncology-academy>



**Dr. med. Luca Afferi** (29) is a junior doctor in the Department of Urology at Cantonal Hospital Lucerne (LUKS). He was mentored by the SAKK Young Oncology Academy in 2022.

“ From my perspective, taking part was a unique opportunity to become a better doctor and researcher. I've improved my presentation skills, expanded my network in Switzerland and been able to embark on new scientific collaborations.



**Dr. med. Kira-Lee Koster** (35) works in the Clinic for Medical Oncology and Haematology at Cantonal Hospital St.Gallen. She is interested in thoracic cancer and phase I trials.

“ I'm very glad I was able to take part. I had the opportunity to engage with dedicated colleagues and make a lot of new contacts. I hope these associations will last far beyond the Young Oncology Academy.



**Dr. med. Bich Doan Nguyen-Sträuli** (35) works at University Hospital Zurich, the University of Zurich and in the Institute of Molecular Health Sciences at ETH Zurich. She specializes in gynecological oncology, liquid biopsies and circulating tumor cells.

“ The Young Oncology Academy has helped me broaden my horizons. I've met interesting people and expanded my knowledge.



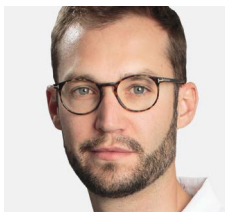
**Dr. med. Martina Bertschinger** (35) works at Cantonal Hospital Winterthur, where she specializes in hemato-oncological diseases.

“ The Young Oncology Academy gave me a chance to deepen my knowledge of my field and expand my network. Thank you for the opportunity.



**Dr. med. Natacha Bordry** (35) works at Geneva University Hospitals (HUG) where she specializes in medical oncology.

“ The Young Oncology Academy enabled me to make new contacts. I look forward to conducting clinical trials with SAKK in the future.



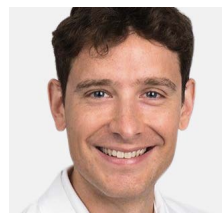
**Dr. med. Nils Degrauwe** (34) works at Lausanne University Hospital (CHUV) and specializes in medical oncology.

“ The Young Oncology Academy gave me the chance to work with young and experienced doctors, and get to know different areas of cancer treatment. As a result, I was able to expand my knowledge of clinical cancer research.



**Dr. med. Eva Heilmann** (35) works in the Hematology Clinic at University Hospital Basel. She is a specialist in general internal medicine and is training to specialize in hematology.

“ Any doctor who wants to give patients the best possible care should be aware of recent trial data and take part in trials. The Young Oncology Academy provides a very good springboard for doing so. Furthermore, it allows participants to make contacts across Switzerland— with experienced experts as much as with young, motivated doctors from a wide range of specialist disciplines.



**Dr. med. Umberto Maccio** (32) is a senior physician at the Institute of Pathology and Molecular Pathology at University Hospital Zurich. He specializes in molecular pathology, omics data, FISH, general histopathology, autopsy and teaching.

“ Success in medicine can only be achieved by interdisciplinary teamwork.



**Dr. med. Alexandros Lalos** (35) is a junior doctor working in visceral surgery at University Hospital Basel

“ Nietzsche once said: “He who would learn to fly one day must first learn to walk and run and climb and dance; one cannot fly into flying.” The Young Oncology Academy gave me the opportunity to build a solid foundation for my future in medical science.

# Financial Statements

## Balance sheet

As at December 31 in CHF	Notes	2022	2021
<b>Assets</b>			
Cash and cash equivalents		11,853,908	9,752,064
Accounts receivable	1	1,523,100	2,700,005
Other accounts receivable		176,016	395,076
Prepaid expenses and accrued income	2	1,308,009	722,403
<b>Total current assets</b>		<b>14,861,033</b>	<b>13,569,548</b>
Financial assets	3	15,769,848	18,364,948
<b>Total fixed assets</b>		<b>15,769,848</b>	<b>18,364,948</b>
<b>Total assets</b>		<b>30,630,881</b>	<b>31,934,496</b>

As at December 31 in CHF	Notes	2022	2021
<b>Liabilities</b>			
Accounts payable	4	1,549,363	2,152,355
Other accounts payable		425,777	228,929
Accrued liabilities and deferred income	5	15,827,814	15,698,855
<b>Total short-term liabilities</b>		<b>17,802,955</b>	<b>18,080,139</b>
<b>Total long-term liabilities</b>		<b>-</b>	<b>-</b>
"Education Grant" fund		35,000	-
"Special purpose" fund		217,932	217,932
"Hubacher" fund		8,806,449	10,216,653
<b>Total special purpose fund capital</b>		<b>9,059,382</b>	<b>10,434,586</b>
<b>Organizational capital</b>			
Free capital as at January 1		3,419,771	3,625,550
Group result		348,773	-205,779
Free capital as at December 31		3,768,544	3,419,771
<b>Total organizational capital</b>		<b>3,768,544</b>	<b>3,419,771</b>
<b>Total liabilities</b>		<b>30,630,881</b>	<b>31,934,496</b>

# Statement of operations

January 1 to December 31 in CHF	Notes	2022	2021
<b>Operating income</b>			
Research contributions SERI		5,830,628	5,891,000
Research contributions SCL		118,900	159,450
Research contributions SCR		1,326,811	1,036,509
Research contributions SSKK		100,000	100,000
Research contributions, third parties		676,819	280,483
Research contributions, Swiss health insurers		1,811,281	1,497,631
Income from industry partnerships		3,952,784	3,435,940
Income from foreign study groups		771,281	181,511
Income from Cancer Bulletin		–	173,377
Income from Patient Advisory Board		52,115	50,028
Donations, bequests, legacies		159,614	548,798
Miscellaneous income		2,046,446	1,573,001
Losses on receivables		87,195	158,307
<b>Total operating income</b>		<b>16,933,875</b>	<b>15,086,034</b>
		<b>100.0 %</b>	<b>100.0 %</b>

January 1 to December 31 in CHF	Notes	2022	2021
<b>Operating costs</b>			
Miscellaneous trial-related expenses		–1,292,567	–2,010,084
Research contributions IBCSG, ETOP		–	–100,322
Research contributions, sites		–3,161,808	–1,790,437
Events, congresses and hospitality expenses		–1,306,096	–1,204,637
Other operating expenses		–103,384	–78,009
<b>Total operating expenses</b>		<b>–5,863,856</b>	<b>–5,183,489</b>
		<b>–34.6 %</b>	<b>–34.4 %</b>
<b>Interim result 1</b>		<b>11,070,019</b>	<b>9,902,545</b>
		<b>65.4 %</b>	<b>65.6 %</b>
<b>Collaboration expenses</b>			
Personnel expenses	6	–8,273,627	–8,110,929
Other collaboration expenses		–1,646,420	–1,124,305
<b>Total collaboration expenses</b>		<b>–9,920,046</b>	<b>–9,235,234</b>
		<b>–58.6 %</b>	<b>–61.2 %</b>
<b>Interim result 2</b>		<b>1,149,973</b>	<b>667,312</b>
		<b>6.8 %</b>	<b>4.4 %</b>
<b>Financial result</b>			
Financial income		189,201	904,342
Financial expenses		–1,432,480	–315,110
<b>Total financial result</b>		<b>–1,243,279</b>	<b>589,231</b>
		<b>–7.3 %</b>	<b>3.9 %</b>
<b>Interim result 3</b>		<b>–93,306</b>	<b>1,256,543</b>
		<b>–0.6 %</b>	<b>8.3 %</b>



January 1 to December 31 in CHF	Notes	2022	2021	
<b>Out-of-period result</b>				
Out-of period income		442,079		–
Out-of-period expenses		–		–1,462,322
<b>Total out-of-period result</b>		<b>442,079</b>	<b>2.6 %</b>	<b>–1,462,322</b> <b>–9.7 %</b>
<b>Annual result</b>		<b>348,773</b>	<b>2.1 %</b>	<b>–205,779</b> <b>–1.4 %</b>

## Cash flow statement

January 1 to December 31 in CHF	2022	2021
<b>+/- Annual gain (+) / loss (–)</b>	<b>348,773</b>	<b>–205,779</b>
+/- Depreciation/value adjustments (+) and additions (–) to fixed assets / appreciation	2,595,100	–1,531,620
+/- Recognition (+) and reversal (–) of provisions	–	–
+/- Depreciation (+) and appreciation (–) of listed short-term assets	–	–
+/- Decrease (+) / increase (–) in short-term receivables	1,395,965	308,196
+/- Decrease (+) / increase (–) in prepaid expenses	–585,606	926,992
+/- Increase (+) / decrease (–) in short-term liabilities	–406,144	–1,494,680
+/- Increase (+) / decrease (–) in deferred income	128,959	6,786,202
+/- Other cash flow-neutral expenses (+) and income (–)	–1,375,204	412,170
<b>= Cash flow from operating activities</b>	<b>2,101,844</b>	<b>5,201,481</b>
– Investments in financial assets	–	–
+ Divestment of financial assets	–	–
<b>= Cash flow from investing activities</b>	<b>–</b>	<b>–</b>

## Statement of changes in capital

January 1 to December 31 in CHF	2022	2021
+/- Assumption (+) / repayment (-) of short- and long-term financial liabilities	-	-
+/- Capital increases (+) / repayments (-)	-	-
<b>= Cash flow from financing activities</b>	<b>-</b>	<b>-</b>
<b>Increase (+) / decrease (-) in cash and cash equivalents</b>	<b>2,101,844</b>	<b>5,201,481</b>
<b>Change in cash and cash equivalents</b>		
As at start of reporting year	9,752,064	4,550,582
As at end of reporting year	11,853,908	9,752,064
<b>Increase (+) / decrease (-) in cash and cash equivalents</b>	<b>2,101,844</b>	<b>5,201,482</b>

2022	Free capital	Net profit + net loss -	Value fluctuation reserve Securities	Total
Holding January 1, 2022	3,419,771	-	-	<b>3,419,771</b>
Change in reserves	-	-	-	-
Annual result	348,773	-	-	<b>348,773</b>
<b>Holding December 31, 2022</b>	<b>3,768,544</b>	<b>-</b>	<b>-</b>	<b>3,768,544</b>
<b>2021</b>				
Holding January 1, 2021	3,625,550	-	-	<b>3,625,550</b>
Change in reserves	-	-	-	-
Annual result	-205,779	-	-	<b>-205,779</b>
<b>Holding December 31, 2022</b>	<b>3,419,771</b>	<b>-</b>	<b>-</b>	<b>3,419,771</b>

## Statement of changes in funds

<b>2022</b>	<b>"Education Grant" fund<sup>1</sup></b>	<b>"Special purpose" fund<sup>2</sup></b>	<b>"Hubacher" fund<sup>3</sup></b>	<b>Total</b>
Holding January 1, 2022	–	217,932	10,216,653	<b>10,434,586</b>
Fund creation	35,000	–	–	<b>35,000</b>
Fund value adjustments	–	–	–1,400,418	<b>–1,400,418</b>
Fund costs	–	–	–9,786	<b>–9,786</b>
Fund use	–	–	–	–
<b>Holding December 31, 2022</b>	<b>35,000</b>	<b>217,932</b>	<b>8,806,449</b>	<b>9,059,382</b>
<b>2021</b>	<b>"Education Grant" fund<sup>1</sup></b>	<b>"Special purpose" fund<sup>2</sup></b>	<b>"Hubacher" fund<sup>3</sup></b>	<b>Total</b>
Holding January 1, 2021	60,000	217,932	9,744,483	<b>10,022,415</b>
Fund creation	–	–	–	–
Fund value adjustments	–	–	922,170	<b>922,170</b>
Fund costs	–	–	–	–
Fund use	–60,000	–	–450,000	<b>–510,000</b>
<b>Holding December 31, 2021</b>	<b>–</b>	<b>217,932</b>	<b>10,216,653</b>	<b>10,434,586</b>

<sup>1</sup> Fund for Janssen-Cilag AG research grant.

<sup>2</sup> Fund for non-industry-associated clinical trials, translational research and training of research specialists.

<sup>3</sup> Fund from the bequest of Dr. Margaretha Hubacher specifically for non-Hodgkin lymphoma research.

# Notes to the 2022 annual financial statements

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

**As at December 31** **2022** **2021**

## Headcount

Bandwidth of full-time equivalents (average for year)	> 50 to 250	> 50 to 250
---	----------------	----------------

**As at December 31 in CHF** **2022** **2021**

## Disclosures on, breakdown of and commentary on items in the balance sheet and income statement

### 1 Accounts receivable

Accounts receivable are generally carried at their nominal amount less specific valuation allowances. A general valuation allowance is recognized for the remainder.

Outstanding accounts receivable gross	1,704,180	2,970,133
Allowance for doubtful accounts	181,080	270,128
<b>Net accounts receivable</b>	<b>1,523,100</b>	<b>2,700,005</b>

### 2 Prepaid expenses and accrued income

Prepaid expenses and accrued income consist mainly of:

Accrued income for trial SAKK 96/12	1,218,308	705,235
-------------------------------------	-----------	---------

**As at December 31 in CHF** **2022** **2021**

### 3 Financial assets

	15,769,848	18,364,948
Of which securities Hubacher fund	8,803,263	10,252,678

Financial assets are carried at their current market value. The SAKK investment rules were taken into account when investing. Fixed assets are managed externally by Swiss banks.

### 4 Accounts payable

Accounts payable are carried at their nominal amount.

### 5 Accrued liabilities and deferred income

	15,827,814	15,698,855
Accrued liabilities and deferred income are made up mainly of the following items:		
Contributions SAKK 96/12	465,318	470,264
Remuneration, executive bodies	–	–
Compensation, sites SAKK 96/12	357,892	1,351,868
Future payments	1,505,160	1,046,866
Solidarity	–	1,185,528
Trial accruals and deferrals	–	4,808,803
Ongoing trial accruals and deferrals	11,017,183	5,459,095

Trial accruals and deferrals comprise all active trials which, according to cost center accounting, show an amount of pre-financing or a profit. The additional trial accruals and deferrals were recognized as liabilities in order to cover measurement risks. The other accruals and deferrals are general accruals/deferrals to ensure that income and expenses are recognized appropriately in the period in which they arise.

January 1 to December 31 in CHF

	2022	2021
<b>6 Personnel expenses</b>		
Gross salaries	6,770,019	6,534,021
Third-party salaries	203,058	267,797
Social insurance	1,139,196	1,092,808
Other personnel expenses	161,353	216,301
<b>Personnel expenses</b>	<b>8,273,627</b>	<b>8,110,929</b>
<b>Auditors' fee</b>		
Fee for auditing services	30,000	16,888
Fee for other services	–	–

January 1 to December 31 in CHF

	2022	2021
<b>Remainder of liabilities from purchase contract-type leasing transactions and other leasing liabilities not maturing or called within 12 months after the balance sheet date.</b>		
Total non-capitalized leasing liabilities	697,983	1,721,494
Liabilities to pension institutions	–	2,183

January 1 to December 31 in CHF

	2022	2021
<b>Notes on extraordinary, non-recurring or out-of-period items in the income statement</b>		
2021: Trial risks arising from restructuring	–	–1,419,998
Auditing costs	–	–25,854
Restructuring costs	–	–16,470
<b>Total out-of-period expenses</b>	<b>–</b>	<b>–1,462,322</b>
2022: Write-back of trial risks	332,079	0
Write-back, 2022: TP, restructuring	100,000	0
<b>Total out-of-period income</b>	<b>432,079</b>	<b>0</b>
<b>Total out-of-period result</b>	<b>432,079</b>	<b>–1,462,322</b>

Cost reductions as a result of the restructuring are included here.

Net release of hidden reserves – –

Events after the balance sheet date: none



### Measurement of research projects:

For the 2022 annual financial statements, research projects were again measured in accordance with the principle of itemized measurement for long-term research projects, comprising identifiable losses on individual trials through to 2028 (measurement at the lower of cost or market value). Any losses incurred after this period are not included since management assumes that additional financing has to be generated for such projects and funding requirements per trial decline significantly toward the end.

Measurement was based on the planning for 2023–2028 prepared by the responsible project managers, which takes account of likely project financing, external and internal trial costs and internal hours less any withdrawals from funds. In addition, the approved, anticipated and non-ring-fenced federal financial contribution for the 2025–2028 period is offset by the sum total for budgeted personnel hours and external costs incurred

by loss-making projects, less project financing. SAKK assumes that funding from the next SERI financing round for 2025–2028 will be the same.

As of the reporting date, the sum total of all trial losses calculated on the basis of itemized measurement means that funds not exceeding the federal financial contributions for 2025–2028 were used. Seasonalized presentation of costs was taken into account.

Based on itemized measurement and the multi-year plan, a provision to ensure the measurement of losses incurred by long-term projects was recognized as of the reporting date. This is reported in the balance sheet under accrued liabilities and deferred income and covers the full total of all individual cumulative losses on trials between 2023 and 2028 in accordance with SAKK's decentralized multi-year planning as at the end of January 2023.

The contributions from SERI for 2021 to 2024 were approved.

### Other information

The negative performance of financial assets during 2022 had a significant impact on financial market ratings as the war in Ukraine progressed, pushing up raw material and energy prices and driving growing inflation throughout the year. SAKK assumes that inflation will subside again and that the impact of the interest rate-driven economic turndown on market valuation could thus gradually have bottomed out. It is currently difficult to assess the effect of recent uncertainty in financial institutions' ratings and their impact on valuations.

# Auditor's report

RÖTHLISBERGER



Report of the statutory auditor to the General Assembly of

**Swiss Group for Clinical Cancer Research, Berne**

## Report on the Audit of the Financial Statements

### Opinion

We have audited the financial statements of Swiss Group for Clinical Cancer Research (the Company), which comprise the statement of financial position as at December 31, 2022 and the income statement, cash flow statement, the statement of changes in equity, the statement of changes in funds for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the financial statements (page 22 to 29) comply with Swiss law and the Company's articles of incorporation.

### Basis for Opinion

We conducted our audit in accordance with Swiss law and Swiss Standards on Auditing (SA-CH). Our responsibilities under those provisions and standards are further described in the "Auditor's Responsibilities for the Audit of the Financial Statements" section of our report. We are independent of the Company in accordance with the provisions of Swiss law and the requirements of the Swiss audit profession, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Other Information

The Board is responsible for the other information. The other information comprises the information included in the annual report but does not include the financial statements and our auditor's report thereon.

Our opinion on the financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements, or our knowledge obtained in the audit or otherwise appears to be materially misstated.

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Partnersgesellschaft

G+S Treuhand AG  
Bern

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RÖTHLISBERGER



If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

**Board's Responsibilities for the Financial Statements**

The Board is responsible for the preparation of the financial statements in accordance with the provisions of Swiss law and the Company's articles of incorporation, and for such internal control as the Board determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Board is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern, and using the going concern basis of accounting unless the Board either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

**Auditor's Responsibilities for the Audit of the Financial Statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with Swiss law and SA-CH will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with Swiss law and SA-CH, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made.
- Conclude on the appropriateness of the Board's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the

RÖTHLISBERGER



related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.

We communicate with the Board regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

**Report on Other Legal and Regulatory Requirements**

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

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

Berne, April 21, 2023 fc/kz  
1434

Dr. Röthlisberger AG

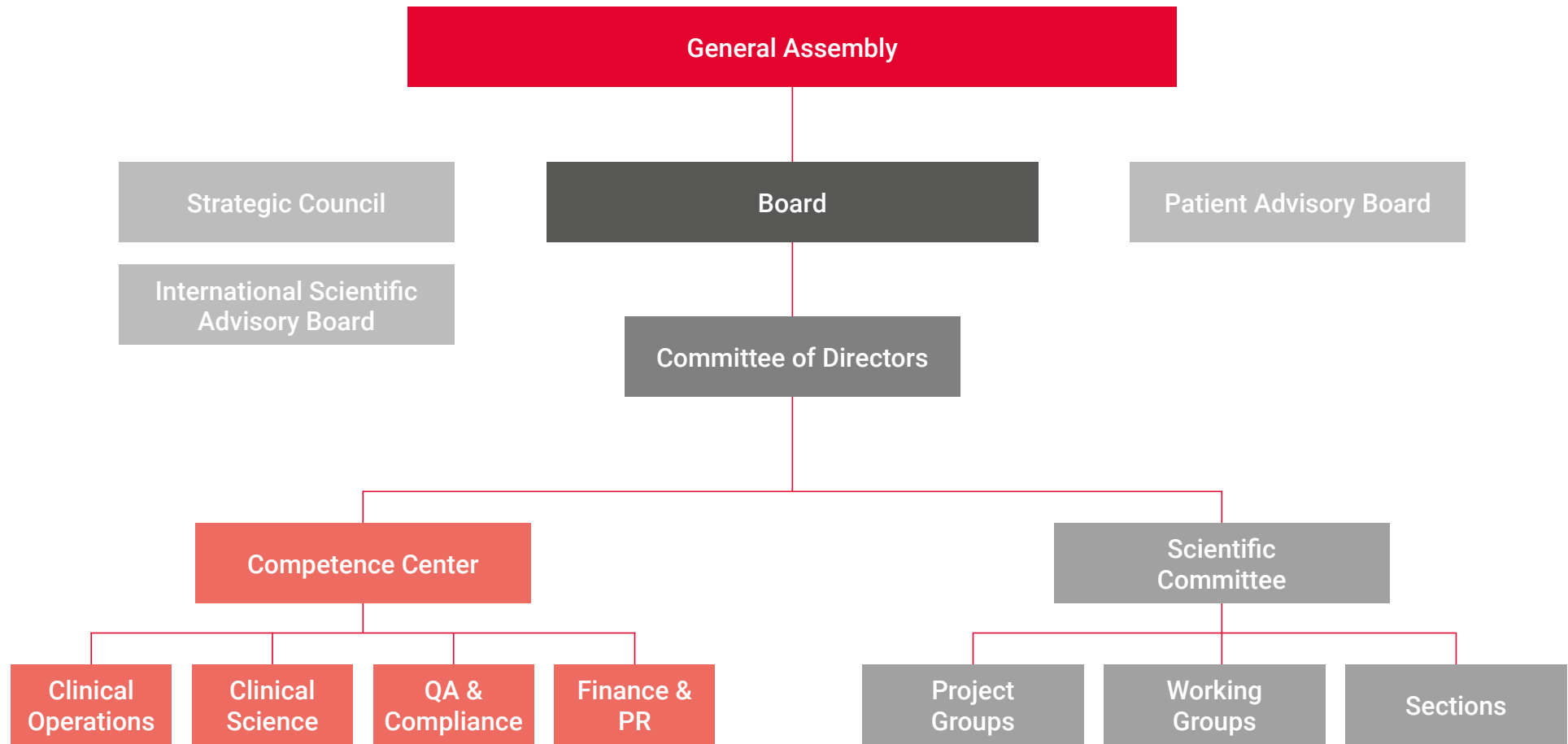
Fabrizio Conoscenti  
Audit Expert  
Authorised audit expert  
Auditor in Charge

Romano Jungo  
Audit Expert  
Authorised audit expert

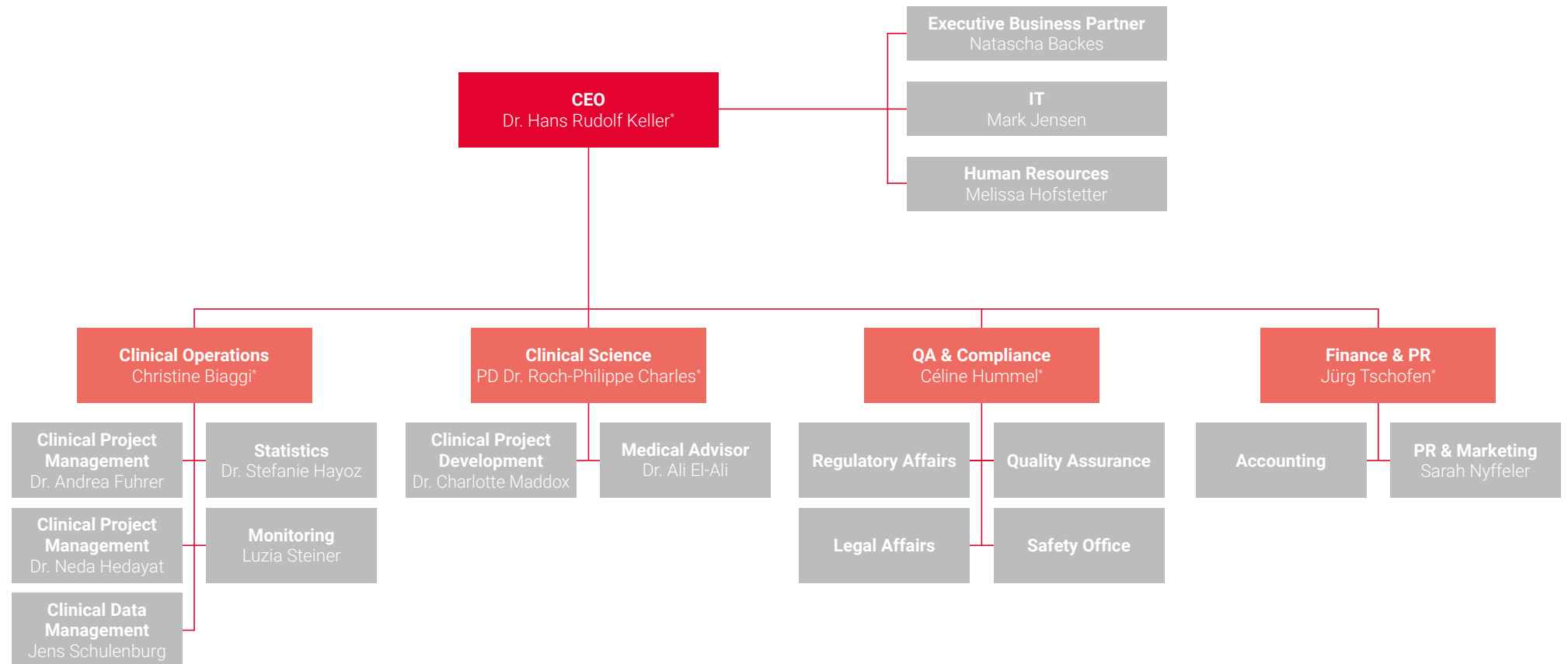
- Financial statements (balance sheet, income statement, cash flow statement, the statement of changes in equity, the statement of changes in funds and notes)  
Balance sheet CHF 30'630'881.00 / Annual profit CHF 348'773.00

# Organization

## SAKK Organization Chart



# SAKK Competence Center Organization Chart



\* Member of the Executive Committee



# Committees

## Board



**Prof. Dr. med. Miklos Pless**  
President



**Marianne Binder-Keller**



**PD Dr. med.  
Richard Cathomas**



**Prof. Dr. med. Urban Novak**



**Dr. oec. HSG Willy Oggier**



**Prof. Dr. med. Dr. phil. nat.  
Sacha Rothschild**

## Committee of Directors



**Dr. Hans Rudolf Keller**  
Chair



**Prof. Dr. med. Martin Früh**



**Prof. Dr. med. Miklos Pless**

## Scientific Committee



**Prof. Dr. med. Martin Früh**  
Chair



**PD Dr. med. Elisabeth Artemis Kappos**



**Dr. med. Brigitta Baumert**



**Dr. med. Thibaud Kössler**



**Prof. Dr. med. Anja Lorch**



**Prof. Dr. med. Christoph Mamot**



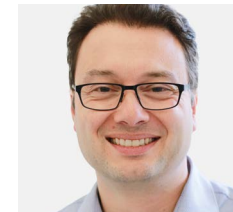
**Dr. med. Berna Özdemir**



**Prof. Dr. med. Chantal Pauli**



**Prof. Dr. med. Davide Rossi**



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



**PD Dr. med. Khalil Zaman**



**Dr. med. Thomas Zilli**

### Advisory members

**Christine Biaggi Rudolf** Chief Operations Officer

**PD Dr. Roch-Philippe Charles** Chief Scientific Officer

**Dr. Stefanie Hayoz** Head of Statistics

## Executive Committee



**Dr. Hans Rudolf Keller**  
Chief Executive Officer



**Christine Biaggi Rudolf**  
Chief Operations Officer



**PD Dr. Roch-Philippe Charles**  
Chief Scientific Officer



**Céline Hummel**  
Chief Quality & Compliance Officer



**Jürg Tschofen**  
Chief Financial Officer

## Strategic Council

**Prof. Dr. med. Nicolas Mach** Geneva University Hospitals (HUG), Chair

**Prof. Dr. med. Martin Berger** Inselspital Bern

**Dr. med. Vèrène Dougoud-Chauvin** Fribourg HFR

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

**Dr. med. Michael Gregor** Cantonal Hospital Lucerne (LUKS)

**Prof. Dr. med. Christoph Mamot** Cantonal Hospital Aarau

**Dr. med. Ioannis Metaxas** Spital Thurgau

**Prof. Dr. med. Roger von Moos** Cantonal Hospital Graubünden

**Prof. Dr. med. Jakob Passweg** University Hospital Basel

**PD Dr. med. Arnoud Templeton** Claraspital

**PD Dr. med. Khalil Zaman** Lausanne University Hospital (CHUV)

**Prof. Dr. med. Thorsten Zenz** University Hospital Zurich

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

**Prof. Dr. med. Daniel Zwahlen** Cantonal Hospital Winterthur

## International Scientific Advisory Board

**Prof. Odd Terje Brustugun** Oslo, Norway

**Dr. Laurence Collette** Brussels, Belgium

**Alexandra Darimont** Hamburg, Germany

**Prof. Dr. med. Cai Grau** Aarhus, Denmark

**Prof. Dr. med. Volker Heinemann** Munich, Germany

**Prof. Dr. Peter Johnson** Southampton, United Kingdom

**Prof. Bertrand Tombal** Leuven, Belgium

**Prof. Dr. med. Peter Wild** Frankfurt, Germany

## Patient Advisory Board

**Dr. Sander Botter**

**Dr. Tourane Corbière**

**Aldo Fiscalini**

**Dr. Ursula Ganz-Blättler**

**Helga Meier Schnorf**

**Rosmarie Pfau**

**Dr. Isabelle Roos**



# Our Specialized Bodies



# Project Groups

Breast Cancer

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Developmental  
Therapeutics

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Gastrointestinal Cancer

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Lung Cancer

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Lymphoma

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Urogenital Tumors

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## Breast Cancer

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### President

**Dr. med. Andreas Müller** Cantonal Hospital Winterthur

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Following a challenging year in 2021, the Project Group Breast Cancer's activities picked up substantially during 2022. In the course of the year, we were able to enroll 259 patients in clinical trials (all interventional trials). 44 Swiss sites contributed between one and 28 patients.

We accrued 16 patients in IBCSG trials (5 patients in IBCSG 55-17 TOUCH, which investigates a chemotherapy-free regimen in postmenopausal patients with early HER2-positive breast cancer, and 11 patients in IBCSG 59-19 POLAR, which tests adjuvant palbociclib in patients with a resected loco-regional relapse).

We successfully transferred sponsorship of the **TAXIS trial** (formerly SAKK 23/16, European Axilla Study) to the Oncoplastic Breast Consortium (OPBC) in Basel. The trial is now being conducted under the extended name OPBC-03 / SAKK 23/16 / IBCSG 57-18 / ABCSG-53 / GBG 101. This important surgical phase III trial with 1,500 patients will answer the question of whether tailored axillary surgery in clinically node-positive breast cancer is non-inferior to a conventional axillary dissection. Our group remains committed to this trial and contributed another 153 patients during 2022. Cumulative accrual is now 644 patients, of whom 541 are from Swiss SAKK sites.

After a suspension during 2021, the **REDUSE trial (SAKK 96/12)** resumed its accrual. This large phase III non-inferiority trial with 1,380 patients investigates optimal denosumab dosage in bone metastasis. In 2022, our sites contributed another 68 patients, resulting in a cumulative accrual of about 1,300 patients. We expect to complete accrual for this trial at the end of 2023.

In addition, sponsorship of the VISION I trial had to be transferred so that it now runs under the name of **HIRS-LANDEN 01 / SAKK 23-18**. Accrual was resumed this year and 22 patients were enrolled by SAKK sites. This trial investigates patients after neoadjuvant chemotherapy with complete remission (confirmed by imaging) to see whether residual microscopic disease can be detected with sufficient sensitivity by means of biopsies. If this trial reaches its endpoint, it will serve as the basis for a further generation of trials that will aim to treat patients with complete remission after neoadjuvant chemotherapy without surgery.

In 2022, five articles on SAKK or IBCSG trials authored or co-authored by members from our group were published in peer-reviewed journals (two on our own trials SAKK 21/12 and SAKK 25/14, and three on IBCSG trials). We were present at the San Antonio Breast Cancer Conference 2022 with three posters (one from SAKK 22/99 and two from TAXIS OPBC-03 / SAKK 23/16); one of the TAXIS posters was even selected for the Spotlight Poster Discussion Session. The POSITIVE trial (IBCSG 48-14), which demonstrates the safety of a two-year interruption in adjuvant endocrine treatment in women who want to become pregnant was presented in a General Session. 39 of the 516 patients in this trial were from SAKK. Another poster from SAKK 95/17 was presented at the European Breast Cancer Conference.

Looking ahead to 2023, we aim to open two proprietary SAKK trials, one in the neoadjuvant and one in the meta-static setting.

## Developmental Therapeutics

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### President

**PD Dr. med. Anastasios Stathis**

Oncology Institute of Southern Switzerland (IOSI)

### Vice presidents

**Dr. med. Dr. rer. nat. Christian Britschgi**

University Hospital Zurich

**Dr. med. Martina Imbimbo**

Lausanne University Hospital (CHUV)

**Prof. Dr. med. Dr. phil. nat. Markus Jörger**

Cantonal Hospital St.Gallen

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The SAKK Project Group Developmental Therapeutics (PG DT) was successfully launched in November 2019 from the merger of the former New Anticancer Treatments (NAT) project group with the Immunotherapy (IO) and Molecular Oncology (MO) working groups. By restructuring in this way, we are able to make optimal use of the expertise of all members and to have robust trials in the immunotherapy and non-immunotherapy fields, potential combinations between the two fields, and strong translational programs. The PG DT will therefore have a broadened focus on innovation in oncology as well as an expanded member base. On September 30, 2022, the group elected its new president (A. Stathis) and two new vice presidents (M. Imbimbo and M. Jörger). A core team (including the president, all vice presi-

dents, and Dr. med. I. Colombo, Prof. Dr. med. F. Bertoni, Dr. med. Dr. phil. nat. S. Häfliger, Dr. K. Homicsko, and Prof. Dr. med. R. von Moos) was also established with the aim of determining the group's strategy.

Following the restructuring of SAKK, the PG DT was able to reactivate all ongoing clinical trials, except for SAKK 66/18 which was prematurely terminated. During 2022 the following trials were active for enrollment: **SAKK 67/20** (PI I. Colombo) evaluating the safety and tolerability of a new micellar docetaxel compound developed by Vivesto in patients with metastatic, castration-resistant prostate cancer. The trial is currently ongoing and enrolling patients in the dose escalation part.

**SAKK 65/16** (PI D. Hess) evaluating the new liposomal doxorubicin TLD-1 (Talidox) developed by Bern-based company Innomedica. Following completion of the phase I dose-finding part in 2021, the trial is currently evaluating the pharmacokinetics of the compound, including a pharmacokinetic comparison with Caelyx in patients with selected solid tumors. This part of the trial is approaching the planned total number of patients, and results are expected in 2023.

Two previously active trials completed enrollment during 2022 and results are expected in 2023: **BASILEA CDS-002** evaluating the colchicine site inhibitor lisavanbulin in patients with relapsing, EB1-positive glioblastoma, and **SAKK 11/16** evaluating cell-based antitumor immunization MVX-ONCO-1 (PI O. Michielin). **SAKK 66/17** (PI M. Jörger), a trial that combines tumor laser ablation with intratumoral injection of the new immune stimulatory compound IP-001 (Immunophotonics), successfully completed the initial safety phase and reopened accrual in Q1 2022. Building on the successful collaboration between SAKK and Immunophotonics, an international trial in which SAKK is participating was activated in November 2022. This trial is investigating a combination of radio-frequency ablation (RFA) and IP-001 in patients with advanced lung cancer, soft tissue sarcoma, or colorectal cancer.

Finally, **SAKK 69/17** evaluating the ATR inhibitor BAY-1895344 reopened accrual from patients with mantle cell lymphoma.

The PG DT also developed and submitted for regulatory approval a retrospective project (PI A. Stathis) that aims to analyze patient-level data of patients enrolled in phase I trials sponsored by SAKK. The results of this project are expected in 2023 and will give the opportunity to analyze the outcomes of patients treated in phase I trials within the SAKK network in the last twenty years.

2022 was also very successful in terms of scientific production. Four manuscripts reporting on trials that were conducted by the group alone or in collaboration with other SAKK groups were published:

- SAKK 80/20, Outcome and prognostic factors of COVID-19 infection in Swiss cancer patients: Final results of SAKK 80/20 (CaSA) Joerger et al., *Cancers*;
- SAKK 41/16: Population pharmacokinetic analyses of regorafenib and capecitabine in patients with locally advanced rectal cancer (SAKK 41/16 RECAP) Schmulenson et al., *BJCP*;
- SAKK 35/15: A phase I trial of obinutuzumab in combination with venetoclax in patients with previously untreated follicular lymphoma, Stathis et al., *Blood Adv*;
- SAKK 06/14: Results of a phase II single-arm clinical trial assessing efficacy, safety, and tolerability of recombinant Bacillus Calmette Guérin (rBCG) VPM1002BC in patients with high-grade non muscle-invasive bladder cancer recurrence after BCG induction with or without BCG maintenance therapy – SAKK 06/14 Rentsch et al., *Eur Urol Oncol*;
- Abstracts: Five abstracts were presented at major meetings: SAKK 11/16 Mach et al., CICON; SAKK 41/16 Bastian et al., ESMO, SAKK 57/16 Digkila et al., ESMO; SAKK 65/16 Hess et al., ASCO; SAKK 66/17 Joerger et al., ESMO IO).

Looking into the future, the group is active in discussions within SAKK as well as with the pharmaceutical industry on the initiation of new phase I trials involving the SAKK phase I network along with other SAKK groups.

## Gastrointestinal Cancer

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### President

**Dr. med. Alexander Siebenhüner**

Clinic for Hematology & Oncology, Hirslanden Zurich

### Vice president

**PD Dr. med. Sara De Dosso**

Oncology Institute of Southern Switzerland (IOSI)

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There was a change at the helm of the Project Group Gastrointestinal Cancer (PG GI) at the start of the year. In March 2022, Dr. med. Alexander Siebenhüner was elected president of the group, while PD Dr. med. Sara De Dosso was elected vice president. We would like to take this opportunity to thank Prof. Dr. med. Dr. phil. Andreas Wicki for his many years of dedicated work on behalf of the PG GI and are delighted that he will continue to support us as the group's liaison person on the SAKK Scientific Committee.

2022 was a challenging year for the PG GI. Whereas accrual for certain trials was completed during 2021 (RECAP, phase II DANTE trial), there were no open trial programs for gastrointestinal cancer during 2022. Furthermore, the process of renewal within SAKK and the financing regimes that now have to be fulfilled present a certain challenge with respect to new trial programs, particularly if adequate sponsorship is still to be secured. This presents a major challenge for purely academic

trials in particular, since such trials generally have no sponsorship when the proposal is drawn up. As a result, it was not possible to open either accrual points or new sites. This also complicated matters as regards sites' voting rights, as a result of which special provisions for votes on ongoing processes in the PG GI were introduced for 2022 and early 2023.

As regards publications and abstracts, several studies published data not only on their ongoing results but also on their final results. The surgical outcome and pathological regression rate from phase II of the DANTE trial were presented at ASCO 2022. Prof. Dr. med. Dr. phil. Markus Jörgler and colleagues also presented data on the dose escalation part of SAKK 65/16 for TLD-1 in cholangiocarcinoma and other tumor types at ASCO 2022. Dr. med. Sara Bastian presented a poster containing data from SAKK 41/16 (RECAP) at ESMO 2022, while Prof. Dr. med. Rupert Langer gave a presentation on the translational part of SAKK 75/08 at the semi-annual meeting in November 2022. In connection with this, Dr. med. Alexander Siebenhüner will be providing a further analysis of ESCC patients receiving aEGFR treatment as part of a multicenter cooperation project with the EORTC, which is being partly financed by an EORTC Young Investigator award (grant to Dr. med. Siebenhüner).

Phase III of the DANTE trial offers a look ahead to forthcoming trials. Over 400 patients will take part in the trial, in which SAKK and the sites operated by the Working Group for Internistic Oncology in the German Cancer Society (AIO) will be participating. It will investigate the value of atezolizumab as an adjunct to perioperative FLOT chemotherapy in terms of response and survival in esophageal cancer. Patients must meet one of the following inclusion factors: MSI high, TMB>10, EBV posi-

tive, CPS >1. The final protocol is expected in early 2023 with the trial tentatively scheduled to start in Q2/Q3 2023. We look forward to working with AIO again.

One of the new clinical trials about to start is a TIL trial in GI cancers with microsatellite instability. Prof. Dr. med. Dr. phil. George Coukos is playing a major role in developing and progressing this trial. We sincerely hope that full funding of the trial will be achieved and that it can start in 2023. Other initiatives such as a registry for pancreatic cancer will also hopefully pick up speed in 2023 – PD Dr. med. Sara De Dosso, who had the idea, is putting a lot of energy into this project. Dr. med. Thibaud Koessler remains extremely active in the SAKK's GI group and is working on a project involving colorectal cancer and a project involving liquid biopsy. Furthermore, Dr. med. Ralph Fritsch is planning a project involving BRAF-mutated treatment-refractory colorectal cancer.

Finally, following an application and selection phase, a core group was formed within the PG GI in September 2022. At present, virtual meetings are held every four weeks to discuss not only trial strategies but also the course of ongoing projects and to support the course of upcoming projects with the responsible PIs. To provide comprehensive financial support, in December 2022 SAKK set up a grant with provision for CHF 1 million in funding for a research project. The competition attracted various proposals addressing gastrointestinal cancer and we are confident that one of these projects will be selected.

I have no doubt that this resourceful and committed research group, supported by the core group and our external advisor Prof. Dr. med. Florian Lordick, can look confidently ahead to 2023 and beyond.

# Leukemia

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## President

**Prof. Dr. med. Thomas Pabst** Inselspital Bern

## Vice president

**Dr. med. Corinne Widmer-Widler**

University Hospital Basel

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After two challenging years due to the COVID-19 pandemic and SAKK-related issues, 2022 turned out to be a success for the Project Group Leukemia (LPG). Thanks to the continuous support of the SAKK Competence Center and the leukemia sites, the open trials continued without further interruption. In particular, the impressively recruiting **CLL-17** trial achieved its final accrual at the end of 2022 with a robust Swiss participation despite the limited recruitment period. For 2023, the **CLL-18** trial is scheduled to be submitted to the authorities with the start of recruitment estimated for Q1 2024. This trial will address, besides the application of BTK inhibitors, the important issue of the timing of MRD assessments.

The **HOVON 150** and **156** trials, with their personalized and curative approaches for young, fit AML patients, showed a steady recruitment in the sites. Both trials address the need to improve first-line treatment of patients with IDH1 or IDH2 mutations (HOVON 150) or FLT3 mutations (HOVON 156). An important step forward was also achieved in the preparation of the **HOVON 501** trial, which will randomize the addition of venetoclax to standard chemotherapy to improve the treatment of FLT3wt AML patients. The initial dose-finding part has already started in Germany, and thanks to the support of the SAKK Committee of Directors, the interested Swiss sites will hopefully have the opportunity to enroll patients in this trial at the end of 2023.

Progress has also been made in trials for AML patients not planned for intensive therapy. In 2022, the EVOLVE consortium (**HOVON/SAKK-AMLSG-NCRI**) defined the future trial framework: As a first project, the combination of azacytidine (Onureg) and venetoclax as an all-oral therapy for unfit patients with AML will be planned as a phase II single-arm trial. Furthermore, the trial investigating the combination of azacytidine/venetoclax versus azacytidine/venetoclax/ivosidenib in IDH1-mutated AML patients is in preparation (based on the positive AGILE trial). The activation of both trials is scheduled for early 2024. The participation of SAKK is yet to be evaluated. Finally, there are plans for a HOVON/SAKK randomized trial of TP53-mutated AML to test the oral addition of ATO: azacytidine/venetoclax versus azacytidine/venetoclax/oral ATO (SY-2021) in a 1:2 randomization. SAKK participation will be decided at the end of 2023.

The organization of the **ALL SAKK/GRAALL** follow-up trial (GRAALL 2022) continues to face financial hurdles due to the very innovative but complex protocol. However,

the group is optimistic that the protocol will be successfully activated and there will be ongoing support from the group.

A promising potential participation of the group was discussed in the **FIAMMA** project (Chimeric antigen receptor (CAR) T cell immunotherapy for children and adults with relapsed acute myeloid leukemia). Phase I of the project will start in 2023. The group will evaluate active participation after completion of phase I.

The scientific output of the group remained stable with a **publication** on the HOVON 103 trial results in *Leukemia*, as well as submission of the CLL13 trial to *NEJM*, and the HOVON/SAKK 92, 102, 103 and 132 trials to *Frontiers in Oncology*. The HOVON 132 results were accepted as an **oral presentation** by ASH.

In March 2022, the group elected Dr. med. Corinne Widmer-Widler from University Hospital Basel as its new vice president. The group is happy to have more younger colleagues interested in active participation in the group.

Finally, with great interest, the new core team of the group was defined with the aim of simplifying and, if possible, accelerating the access and selection of new trials. However, one of the main, challenging tasks will be to select a focused set of trials from the large scope of hemato-oncological diseases, and to define an implementable strategy for the SAKK LPG for the next five years.

# Lung Cancer

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## President

**Prof. Dr. med. Alessandra Curioni-Fontecedro**

Cantonal Hospital Fribourg HFR

## Vice presidents

**Dr. med. Laetitia Mauti** Cantonal Hospital Winterthur

**Prof. Dr. med. Alfredo Addeo**

Geneva University Hospitals (HUG)

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In 2022, numerous structural changes took place, as well as the reorganization of SAKK. A new president was elected (Prof. Dr. med. Alessandra Curioni-Fontecedro), as was an additional vice president (Prof. Dr. med. Alfredo Addeo). A core group representing the heterogeneity of the group was established, with members including a radio-oncologist (PD Dr. med. Tobias Finazzi), a surgeon (Prof. Dr. med. Isabelle Schmitt-Opitz), and Prof. Dr. med. Martin Früh as representative of the SAKK Scientific Committee. A new strategy for 2023 including various priorities was developed at the first core team meeting. Thanks to the broad portfolio of trials, new sites acquired voting rights in 2022, bringing the total to 17, with no sites losing voting rights this year.

For operable NSCLC, **SAKK 16/18** has been recruiting patients to undergo chemo-radiotherapy and durvalumab, followed by surgery and then treated with maintenance durvalumab; this trial is led by Dr. med. Laetitia Mauti and is the follow-up trial to SAKK 16/14. The following presentations on SAKK 16/14 were held in 2022: SAKK 16/14 CyTOF (D. Schmid), accepted as a poster by WCLC; SAKK 16/14 Pathology (B. Sobottka), accepted as an oral presentation by WCLC; and SAKK 16/14 CD8 T cell analysis (B. Sobottka), accepted as an oral presentation by DGHO. Moreover, two manuscripts have been accepted for publication, presenting the analysis of data from patients included in trial SAKK 16/xx: K. Furrer et al., published in *J Thorac Cardiovasc Surg*; and D. König et al., published in *ESMO Open*.

For metastatic NSCLC, **SAKK 19/17** recruited all patients in 2022. This trial included patients with a performance status of 2 to receive durvalumab. The PI, Dr. med. Michael Mark, reported on the initial challenges of recruitment, since this dedicated trial tries to answer an as yet unsolved question about the role of immunotherapy and the possible toxicity for this frequent population of patients. Meanwhile, the following manuscripts were published in 2022 from the SAKK 19/xx trials: SAKK 19/18 (rogaratinib in pretreated squamous-cell NSCLC; A. Addeo, published in *Lung Cancer*) and SAKK 19/16 (phase I binimetinib added to standard chemo in KRAS+ advanced NSCLC; P. Frösch, published in *Lung Cancer*).

For patients in further line, **SAKK 17/18** completed recruitment within a very short time back in 2021, and the analysis of outcome will be presented at an international conference in 2023.

For extensive-stage SCLC, **SAKK 15/19** has so far recruited four-fifths of the planned number of patients. This trial examines the role of radiotherapy consolidation after chemo-immunotherapy (with durvalumab) in extensive disease. The PI, Prof. Dr. med. Alfredo Addeo, reported on the initial difficulty in recruiting patients, but this issue has now been resolved, and the last patient is expected to be included at the beginning of 2023.

For limited-stage SCLC, the PI, S. Rothschild, has established a collaboration with the Scandinavian trial group to recruit patients in the **Achilles** trial. This trial aims to understand the role of atezolizumab consolidation in limited-stage SCLC. This trial investigates a very important issue in this small population of patients; such international collaboration has supported the success of recruitment and underlines the need for trials for these patients.

For mesothelioma, the **SAKK 17/18** ORIGIN trial completed recruitment of the patients from the mesothelioma cohort in 2022. The trial has been developed for pre-treated patients who are not responding to standard treatment, in order to evaluate the combination of gemcitabine and atezolizumab. The fast pace of recruitment for this trial demonstrates the tremendous need for new therapies in this setting.

From the previously concluded **SAKK 17/16** trial (lurbinectedin in relapsed mesothelioma), a manuscript about follow-up and translational data (M. Mark) was published in *ESMO Open* in 2022.



### Collaborative Trials on Thoracic Cancers

Several collaborative projects are ongoing with the valued collaboration of ETOP.

For oligometastatic NSCLC, these include the **CHES** trial (M. Gückenberger, I. Opitz, A. Curioni). All patients have been included to receive chemotherapy, durvalumab and SBRT to all metastatic sites, followed by local definite treatment (surgery or radiotherapy); this trial will now be amended from durvalumab alone to combination therapy with tremelimumab.

For metastatic NSCLC, the **ABC-lung trial** completed recruitment of pretreated patients with EGFRmut to receive atezolizumab-bevacizumab + pemetrexed vs. the IMpower150 regimen. The SAKK sites have contributed to this trial as expected under the local lead of Martin Früh.

For mesothelioma: the **BEAT-MESO** trial investigated the role of chemotherapy + bevacizumab ± atezolizumab in untreated patients. In 2021, the primary endpoint of the trial was changed to overall survival, thus increasing the number of patients included, and all patients have now been recruited with very good participation from the SAKK sites under the local lead of Dr. med. Amina Scherz and Prof. Dr. med. Alessandra Curioni-Fontecedro.

The success of this collaboration is also shown by the associated publications:

**ETOP ALERT** (alectinib in RET-rearranged NSCLC, C. Britschgi): published in *Lung Cancer*.

**ETOP BOOSTER** (osimertinib-bevacizumab in T790M/EGFR+ NSCLC, M. Früh, C. Britschgi, M. Pless): published in *Annals of Oncology*.

**ETOP PROMISE-meso** (prognostic score, A. Addeo, A. Curioni, O. Gautschi, W. Janthur, S. Peters): published in *Lung Cancer*.

### Outlook

Several projects are scheduled for launch in 2023, with trials translating findings from preclinical data to clinical trials in NSCLC, SCLC, and mesothelioma. Registries are also under development.

## Lymphoma

### President

**Prof. Dr. med. Francesco Bertoni** USI

### Vice president

**Prof. Dr. med. Thorsten Zenz** University Hospital Zurich

In 2022 our group included 44 patients in a total of four clinical and interventional trials (three of them closed after March/April 2022), and 16 more in the ECML Registry which reopened in June 2022. These numbers are slightly higher than in 2021, but still much lower than in the previous years. The main reason is that we still lack trials for patients affected by some of the most common hematologic cancers, such as follicular lymphoma and multiple myeloma. Moreover, the HD21 trial for Hodgkin lymphoma patients closed in March 2022. However, **SAKK 38/19** for diffuse large B-cell lymphoma (DLBCL) patients in first line has now opened in all the Swiss sites and in three Italian sites. This trial is very important for our group since it was designed by investigators from the Project Group Lymphoma and it is based on very innovative ideas. It is an exploratory multicohort phase II trial exploring the addition of second-generation BTK inhibitor acalabrutinib to standard regimen R-CHOP in a subset of DLBCL patients bearing specific genetic lesions, as defined by liquid biopsy, and also the integration of circulating tumor DNA with PET imaging in treatment.

Once again, the scientific output of the group remained high, with different publications including the primary results of the phase I trial **SAKK 35/15** that explored the combination of obinutuzumab in combination with venetoclax in patients with previously untreated follicular lymphoma, published in *Blood Advances*. Among the abstracts submitted to conferences, there were multiple oral presentations at ASH, EHA, and ISHL12, including the plenary presentation at ASH on the results of the TRIANGLE phase III trial on the efficacy and safety of ibrutinib combined with standard first-line treatment or as a substitute for autologous stem cell transplantation in patients with mantle cell lymphoma.

The group approved participation in two international studies which are expected to open for accrual in 2023: one for elderly CNS lymphoma patients (CNS-PRIMA trial) and one for untreated splenic marginal zone lymphoma patients (IELSG48).

The group also elected Dr. med. Noémie Lang, Prof. Dr. med. Urban Novak and PD Dr. med. Anastasios Stathis as members of its core team, which also includes president Prof. Dr. med. Francesco Bertoni, vice president Prof. Dr. med. Thorsten Zenz, and the Scientific Committee representative, Prof. Dr. med. Christoph Mamot.

Discussions have been held with other European groups to define the new studies for patients with follicular lymphoma, mantle cell lymphoma, and Hodgkin lymphoma and novel trials for these indications will hopefully soon be available again within the SAKK network.

## Urogenital Tumors

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### President

PD Dr. med. Aurelius Omlin OnkoZentrum Zürich

### Vice president

Dr. med. Alexandros Papachristofilou

University Hospital Basel

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### 1. Presentation on SAKK 08/14 – IMPROVE: Investigation of metformin in patients with metastatic castration-resistant prostate cancer (mCRPC) in combination with enzalutamide vs. enzalutamide alone

PD Dr. Christian Rothermundt presented the primary endpoint of SAKK 08/14 at ESMO 2022. The trial accrued 166 patients with advanced castration-resistant prostate cancer and compared the additional benefit of metformin in combination with enzalutamide against enzalutamide on its own. Despite not achieving its primary endpoint, the trial nevertheless offers an opportunity for translational research that could improve our understanding of the effect of metformin in patients with advanced prostate cancer. In addition, the Project Group Urogenital Tumors (PG UG) participated in the STAMPEDE trial, which is investigating the benefits of metformin in a very large patient collective.

### 2. Publication of SAKK 01/10: Single-dose carboplatin followed by involved-node radiotherapy for stage IIA and stage IIB seminoma (SAKK 01/10): a single-arm, multicenter, phase II trial

SAKK 01-10 was published prominently in the November 2022 edition of *The Lancet Oncology*, where it attracted a lot of international attention. It is gratifying to report that follow-up trial **SAKK 01/18** is also making very good progress. By the end of 2022, 99 of the planned 135 patients had been accrued.

### 3. SAKK 06/19: Intravesical recombinant BCG followed by perioperative chemo-immunotherapy for patients with MIBC

SAKK 06/19 in muscle-invasive bladder cancer was successfully opened in spring 2022. This trial is an excellent example of good interdisciplinary cooperation.

The PG UG has several projects at the planning and preparatory stage, and it hopes that it will be possible to expand the portfolio again in the next year or two. Furthermore, the group introduced a core team in 2022. This meets roughly every six weeks in addition to the four fixed team meetings to discuss projects and strategy issues and initiate further action as necessary. The PG UG strategy is in development and will be ratified at the next semi-annual meeting in May.

# Working Groups

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## Imaging in Diagnostic and Therapy Monitoring

### President

**PD Dr. med. Andreas Hötter** OnkoZentrum Zürich

### Vice president

**Prof. Dr. med. Lukas Ebner** Inselspital Bern

The Working Group Imaging in Diagnostic and Therapy Monitoring (WG IDTM) consists of members from the fields of radiology, neuroradiology, and nuclear medicine along with interested individuals from oncology and radio-oncology. It thus forms an interdisciplinary network of clinicians and researchers dedicated to improving diagnostic imaging as well as the prediction and assessment of therapeutic response in oncology patients. Imaging is an integral part of nearly all clinical trials in oncology, as a means of reliable diagnosis and as the method used to assess the response of a tumor to treatment.

The group is involved in clinical trials within SAKK to offer guidance regarding imaging strategies (e.g. determining the best imaging approach to assess response to treatment). Its interdisciplinary approach, combined with the compilation of general strategies into white papers—the first of which has been completed and is expected to be published soon—enables it to maintain availability to advise on imaging questions from other groups.

## Gynecological Cancer

### President

**Prof. Dr. med. Viola Heinzelmann-Schwarz**

University Hospital Basel

### Vice presidents

**PD Dr. med. Intidhar Labidi-Galy**

Geneva University Hospitals (HUG)

**Dr. med. Ursula Hasler-Strub**

Cantonal Hospital Graubünden

**Dr. med. Apostolos Sarivalasis**

Lausanne University Hospital (CHUV)

**Dr. med. Ilaria Colombo**

Oncology Institute of Southern Switzerland (IOSI)

The Working Group Gynecological Cancer (WG GYNE) is continuing its constructive discussions within regular group meetings, developing its own trial proposals and, in parallel, actively participating in collaborative trials within the ENGOT Network.

### Own trials

**SAKK/SCORED\_OvCaR** – the Swiss Registry of Ovarian Cancer. This registry is funded for 500 patients. We are currently in the protocol development phase and aim to start with the first patients by October 2023 at the latest.

The Working Group Gynecological Cancer took the opportunity of the SAKK Network Trial Award to develop two new trial proposals:

1. A trial entitled **“Phase II study of ctDNA guided immune checkpoint-based treatment in MSI-high/dMMR endometrial cancer”** was developed and submitted for the SAKK Network Trial Award by Dr. med. Ilaria Colombo and PD Dr. med. Intidhar Labidi-Galy.

This is a two-part trial which aims firstly to validate the use of ctDNA in predicting the response to immune checkpoint inhibitors in MSI-high/dMMR endometrial cancer and secondly to assess the efficacy of the combination of pembrolizumab and lenvatinib in reversing resistance to single-agent immune checkpoint inhibitors. The proposal is currently being discussed with companies (Sophia Genetics, MSD, Eisai) with a view to securing support. There is a possibility of collaboration through the EORTC Gyne group and this trial will be presented soon.

2. The trial entitled **“Sumes-Trial, a randomized phase III trial on the safety of uterine manipulators in endometrial cancer surgery”** was developed and submitted for the SAKK Network Trial Award by Dr. med. Franziska Siegenthaler. The aim of this multicenter non-inferiority trial is to evaluate the oncological safety of the use of intrauterine manipulators or cervix cups during minimally invasive staging surgery in early-stage endometrial cancer patients.

### Collaborations

#### **RAINBO program**

**Refining Adjuvant treatment IN endometrial cancer Based On molecular profile (RAINBO)**. The working group was prepared to participate in this important international collaborative program, first with the Green Trial and then with the Blue Trial. Unfortunately, after having made several attempts to find financing scenarios, the venture had to be abandoned.

### **DOMENICA trial**

#### **Randomized phase III trial in MMR-deficient endometrial cancer patients comparing chemotherapy alone versus dostarlimab in first-line advanced/metastatic settings (GINECO-EN105b/ENGOT-en13 trial)**

The working group is willing to participate in this important collaborative trial (sponsor: GINECO, French academic group) as no competitive trial is open in this indication. The trial is ready to be opened at Swiss sites.

The aim of the DOMENICA trial is to evaluate the efficacy of dostarlimab in monotherapy in first-line settings in advanced endometrial cancer. It aims to demonstrate in a randomized phase III trial the benefit of dostarlimab compared with the standard of care (carboplatin plus paclitaxel chemotherapy) in order to have a label in Europe.

This trial is particularly important in view of the current development of precision medicine in advanced MMR-deficient endometrial cancer. Patients stand to benefit from this immunotherapy that has shown a high response rate in this setting. Dostarlimab is very likely to become the new standard of care in this setting (entailing a major change of practice).

The trial is supported by the Scientific Committee and has been approved by the Committee of Directors.

### **THE ENGOT HRD European Initiative (EHEI)**

The ENGOT network, launched in December 2019, is a European initiative which aims to evaluate academic HRD tests on a subset of the tumor samples from the PAOLA1 trial to determine reliable and feasible HRD tests. The working group supported the application of Prof. Dr. med. Thomas McKee (HUG) as a representative of Switzerland to validate the academic HRD test developed in Geneva on the PAOLA1 cohort. The work performed by Thomas McKee's team was very successful and led to the validation of 459 samples of Geneva HRD as a prediction for the benefit of olaparib + bevacizumab. The results were presented at the last ENGOT meeting (Copenhagen, October 2022) and as an oral presentation at the last ESGO meeting (Berlin, October 2022)

[https://ijgc.bmj.com/content/32/Suppl\\_2/A238.2](https://ijgc.bmj.com/content/32/Suppl_2/A238.2)

This success highlights the quality of translational research conducted within the SAKK network and the importance of pursuing such strategies with the aim of increasing the visibility and leadership of SAKK at the European level.

## Head and Neck Cancer

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### **President**

**Dr. med. Vittoria G. Espeli**

Oncology Institute of Southern Switzerland (IOSI)

### **Vice president**

**PD Dr. med. Panagiotis Balermipas**

University of Zurich and University Hospital Zurich

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2022 was a year of new beginnings for the Working Group Head and Neck Cancer.

At the semi-annual meeting in May 2022, Dr. med. Vittoria Espeli was elected as the new president and PD Dr. med. Panagiotis Balermipas as the new vice president of the group.

The first important goal was to create a more active group, starting with the recruitment of new members. The working group now includes members from the fields of oncology, radiotherapy, and surgery, and thus forms an interdisciplinary network of clinicians and researchers dedicated to improving the treatment of head and neck cancer.

Secondly, we have set up a core team dedicated to discussing new trial proposals and overseeing conduct of ongoing trials. The core team will meet on a bi-monthly basis to rapidly move forward with proposal development and approval processes. The members of the working group met at the SAKK semi-annual meeting in November 2022. Alongside the exchange of information, two research proposals were presented and evaluated in detail.

The **MaxiVAX trial (SAKK 11/16)** is continuing to recruit actively, albeit outside SAKK and with new sponsors.

The first results have already been presented and appear promising.

The SAKK Scientific Committee and Committee of Directors endorsed the new trial **EORTC-2014 PROLoNg**, with three of our members as either principal investigators or part of the trial steering committee. This is a randomized phase III trial evaluating the role of radiotherapy added to systemic treatment with pembrolizumab for oligometastatic head and neck cancer, and it will be conducted in cooperation with the EORTC as an intergroup trial.

Two new proposals have already been developed and are being evaluated:

- Firstly, a randomized trial of systemic therapy with or without radical local treatment of the primary tumor in head and neck cancer patients with multiple distant metastases.
- Secondly, a randomized trial of systemic treatment sequencing in loco-regionally recurrent head and neck cancer non-amenable to local treatment.

A call for participation is being conducted in the first quarter of 2023.

Overall, the group is motivated and proactive in promoting research in the field of head and neck cancer oncology and we hope to recover the lost ground from the past few difficult years.

## Melanoma

### President

**Dr. med. Joanna Mangana** University Hospital Zurich

### Vice president

**Dr. med. Ioannis Metaxas** Spital Thurgau AG

Due to the major achievements and several approved therapeutic regimens in the melanoma field in recent years, initiating national phase I-II trials is becoming challenging. The **ENiGMA**: open-label, non-randomized, Phase IB trial to characterize the safety, tolerability, and recommended dosage of tinostamustine (EDOS101), a first-in-class alkylating histone deacetylase inhibition (HDACi) fusion molecule, in combination with nivolumab in patients with refractory, locally advanced or metastatic melanoma, finished accrual last year; the trial also includes a translational part under the lead of Prof. Dr. Lukas Flatz. Publication is expected in 2023.

**SAKK 66/17**: Thermal laser ablation and intratumoral injection of IP-001 in patients with advanced solid tumors is recruiting very well in soft tissue tumors, yet recruitment of melanoma patients is challenging. Pleasingly, Bern is set to open as an additional site in addition to Chur and St.Gallen.

Analysis of **CTLA-4 single nucleotide polymorphisms (SNPs)** as possible surrogate markers for the outcome of ipilimumab-containing regimens in melanoma: The first analysis of the project was completed in 2022, with encouraging results in terms of predictive factors for immune-related adverse events in patients having received anti CTLA-4. The results were presented at the last ESMO-IO meeting. The data still need to be validated within large biobanks.

Furthermore, a new proposal under the lead of Dr. med. Ioannis Metaxas on immuno-chemotherapy combination in metastatic melanoma patients with high LDH levels was discussed in detail at the last Working Group Melanoma meeting. The first steps have already taken place and contact with pharmaceutical companies has been initiated.

Prof. Dr. Paolo Ascierto accepted our invitation to join the Working Group Melanoma as an international expert; the members are looking forward to benefiting from his major scientific contribution and expertise.

Lastly, the first meeting to discuss the update of the Swiss melanoma guidelines took place virtually last October. The first draft is on its way; the next meeting is scheduled for early 2023.

### Outlook

- Swiss melanoma guidelines to be updated in 2023
- New melanoma proposals will hopefully be initiated in 2023



## Sarcoma

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### President

**PD Dr. med. Attila Kollàr** Inselspital Bern

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At the initiative, and under the lead of, the SAKK Project Group Developmental Therapeutics, the Working Group Sarcoma was able to evaluate and support national activation of two trials for sarcoma patients. The multicenter phase I/II trial **SAKK 66/17** is investigating the feasibility, tolerability and efficacy of laser ablation combined with intratumoral injection of the new immune stimulatory compound IP-001. With this trial still ongoing, and building on the successful collaboration between SAKK and Immunophotonics, the manufacturer of IP-001, a second international trial under SAKK's lead—**SAKK 69/22**—was initiated. This project is studying a combination of radio-frequency ablation and IP-001 in patients with advanced sarcoma, lung or colorectal cancer.

The presentation of the results of **SAKK 57/16 (NAPAGE)** at the 2022 ESMO Congress in Paris was a major event in terms of our working group's international visibility. The trial shows that palliative chemotherapy in the form of nab-paclitaxel and gemcitabine is an active combination therapy for previously treated soft tissue sarcoma. Despite intensive discussions with the pharmaceutical industry, we were unable to find support for the idea of a follow-on trial to investigate the benefits and tolerability of the same combination plus immunotherapy.

Efforts to participate in an international trial of Ewing sarcoma treatment (**iEuroEwing or INTER-EWING-1**) remained a focal area of our activities in 2022. Both prospective randomized phase III trials with principal investigators Prof. Dr. med. Uta Dirksen (Germany) and Prof. Dr. Bernadette Brennan (United Kingdom) are investigating several important questions relating to the optimal therapy, and maintenance drug therapy in particular, of patients with Ewing sarcoma. Since this sarcoma entity can occur in both children and adults, and patients of any age would be eligible to participate in the trials, we intend to coordinate closely with the Swiss Paediatric Oncology Group (SPOG). As soon as SPOG has decided which trial it would like to participate in, we will evaluate and drive forward collaboration in the context of that trial.

In the future, the Working Group Sarcoma will focus firstly on initiating a new national sarcoma trial, and secondly on maintaining involvement in international trials. The Working Group Sarcoma continues to be a very active and stimulating community. This is reflected in two new projects and proposals for the SAKK Network Award 2022:

- a) Total Neoadjuvant Treatment with HYPeRthermia in high-risk extremity and trunk soft tissue sarcoma (**TNT-HYPE**): A multicenter single-arm phase II proof-of-concept trial
- b) TACE for desmoid tumors

Going forward, successful clinical research into rare cancers such as sarcoma will require optimal national-level collaboration and dedicated support from all stakeholders.

## Supportive Care and Palliative Cancer Care

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### President

**Prof. Dr. med. David Blum** University Hospital Zurich

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The Working Group Supportive Care and Palliative Cancer Care is interested in all topics relating to supportive and palliative care interventions, geriatric oncology, psycho-oncology, and cancer rehabilitation. Several trial proposals were discussed during 2022.

The Board decided to integrate geriatric oncology research into the Working Group Supportive Care and Palliative Cancer Care.

### Ongoing trials

Study assessing patient experiences of cancer care during the COVID-19 pandemic: This is no longer an SAKK trial; however, the group has decided to evaluate the possibility of transforming it into an SAKK registry.



### Planned trials

The **Signal Light trial** aims to investigate different methods of objective prognostication before tumor-directed palliative treatment. It has been submitted to the Board as a piggyback trial for initial assessment (and since approved); the search for a matching clinical trial is in progress and contacts with the Project Group Lung Cancer have been established. The assessment should also include geriatric screening (G-8) together with two signal measures: a dynamometer (hand grip strength, HGS) and a bio-impedance analysis phase angle (BIA/PA).

The **SENS trial** aims to explore the feasibility, acceptability, and appropriateness of an advance care planning (ACP) intervention in the daily practice of a medical oncologist in a pilot trial. Based on the pilot, a larger trial is planned and will be proposed in 2023.

A study proposal on decisional regret and conflict in clinical cancer trials has been submitted. The proposal was approved by the SAKK Scientific Committee on the condition that it will be turned into a large study. It will be held throughout Switzerland, with questionnaires in German, French, and Italian. The search for trials (four or five phase II or III trials) and funding is currently ongoing.

A study on patients' preferences for quality of life (QoL) over length of life (LoL) in oncology is being prepared. The project foresees a small pilot study with 30 gastric and oesophageal cancer patients, asking them about their preference before, during, and after the treatment in order to investigate whether their preferences evolve over time. Additionally, the study seeks to assess whether there is a discrepancy between what treating healthcare professionals believe their patients prefer, and what the patients' actual preferences are.

**MultiAnam:** Multimodal treatment including anamorelin in patients suffering from cancer cachexia. The international MultiAnam trial obtained funding in Norway and Scotland. The proposal has been presented to the Project Group Gastrointestinal Cancer in order to seek funding in Switzerland.

**ePROs and cannabis registry:** This is a registry on medical cannabis using digital reporting through the Consilium Care app that records patients' experiences (QoL and symptoms as well as cannabis dose and cognitive functions). This project is presented to the Section Registries.

## Cellular Therapies

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### President

**Prof. Dr. med. Dr. phil. George Coukos**  
Lausanne University Hospital (CHUV)

### Vice presidents

**PD Dr. med. Francesco Ceppi**

Lausanne University Hospital (CHUV)

**Dr. med. Michael Daskalakis**

Inselspital University Cancer Center UCI

**Prof. Dr. med. Heinz Läubli** University Hospital Basel

**PD Dr. med. Antonia Maria Müller**

University Hospital Zurich

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The core team met on a regular basis and worked together enthusiastically to move cell-based technologies in Switzerland rapidly forward, developing a framework of aims, processes, and milestones. A close collaboration with the Swiss Blood Stem Cells Transplantation (SBST) is in place with Prof. Dr. med. Caroline Arber Barth as representative. The members of the entire working group met twice in 2022 at the SAKK semi-annual meetings. Alongside the exchange of information and lively discussions, interesting research projects were presented and evaluated in detail.

The second interim report regarding the "Establishment of a Swiss network for cell-based immunotherapies in oncology" was submitted to Swiss Cancer Research (SCR) in June 2022. SCR approved the report, thus completing the final step in the establishment of a Swiss network for cellular therapies.

The development of the first SAKK Board-approved pilot trial, **NeoTIL-ACT** (a multicenter pilot trial to assess the feasibility, safety, and efficacy of adoptive transfer of autologous tumor-infiltrating lymphocytes enriched for tumor antigen specificity in GI MSI-HIGH), was ongoing in 2022. As cellular therapies are very expensive, an extensive funding strategy was followed up based on grants and partners, including the Rising Tide Foundation for Clinical Cancer Research (RTFCCR) as well as Swiss Cancer Research (SCR), the Cancer Research Institute (New York), and several other foundations. The SCR, RTFCCR, and other institutions (e.g. Swiss Foundation for Clinical Cancer Research (SSKK), Kurt and Senta Hermann-Stiftung, Stiftung Krebsbekämpfung, and SPS foundation) awarded funding in support of the trial in 2022.

A further two academic non-SAKK trials have been discussed and supported within the group and will be presented and followed up in the group meetings. These include “CAR T cell trial targeting CD70 for hematologic malignancies” by Prof. Dr. med. Caroline Arber Barth and a project in pediatric oncology, “CAR T cells for pediatrics patients”, by PD Dr. med. Francesco Ceppi.

As the regulatory hurdles for T-cell therapies are exceedingly high and change rapidly, we proactively sought dialog with the responsible authorities—the Federal Office of Public Health and Swissmedic—to enable the best possible solutions for the Swiss platform for cellular therapies. The discussions with both authorities were very constructive in moving this field of research forward and providing these highly effective and promising investigational therapies to patients in Switzerland. However, future decisions by the Federal Office of Public Health and Swissmedic on cost compensation for cellular therapies and patient hospital stays strongly depend on the

successful launch and conduct of an initial pilot trial within the Swiss network for cellular therapies. In 2023 the aim is to secure complete funding, open the first clinical trial in the Swiss network, and jointly start implementation of the first translational research projects. The main hurdles in advancing these innovative cellular therapies will remain the same, i.e. funding and regulatory hurdles. We are convinced that together we will be able to surmount these obstacles and ultimately improve cancer care for all our patients.

## CNS Tumors

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### President

**Prof. Dr. med. Patrick Roth** University Hospital Zurich

### Vice president

**Prof. Dr. med. Philippe Schucht** Inselspital Bern

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In 2022 and under its president Prof. Dr. med. Patrick Roth, the Working Group CNS Tumors (WG CNS) continued to provide a platform for exchanging ideas and coordinating research into brain tumor treatment. Interaction remained largely virtual as the medical community eased out of the pandemic-related restrictions. During the spring semi-annual meeting on May 5, 2022, Basilea / CDI-CS-002, PERGOLA, and ReSurge as well as trials with L19-TNF were discussed. The second semi-annual meeting was held on December 5, 2022. PD Dr. Roch-Philippe Charles and the SAKK Clinical Science Unit were introduced, and further collaborations between adult and pediatric neuro-oncological efforts were discussed.

Members of the Working Group CNS Tumors continue to collaborate on a series of clinical trials, such as “Next generation sequencing in adult patients with glioblas-

toma in Switzerland: a multi-center decision analysis” published by PD Dr. med. Thomas Hundtberger (*J Neurooncol.* 2022 Jul;158(3):359–367). The working group continues to work on novel trial protocols to be put into action using the SAKK network. Most members of the working group are now also members of the Swiss Neuro Society—SwissNOS—which, although recently founded, already counts over 60 members. With SwissNOS as a practical platform for promoting and supporting new trials, the Working Group CNS Tumors will have to rethink its strategy and address the difficulties encountered in the past with proposals for trials in neuro-oncology at SAKK.

Prof. Dr. med. Philippe Schucht and Dr. med. Emilie Le Rhun were elected as president and vice president respectively on December 5, 2022.

# Sections

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## Network for Outcomes Research

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### President

**PD Dr. med. Konstantin Dedes** University Hospital Zurich

### Vice president

**Prof. Dr. med. Thomas D. Szucs** Klinik Hirslanden

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In recent years, the main focus of the Network for Outcomes Research has been on health economic analyses (HEA) alongside selected SAKK trials and literature-based modeling.

In 2022, a cost and budget impact analysis of olaparib for BRCA1/2 germline-mutated pancreatic cancer was completed and will soon be submitted for publication. Additional projects on the cost-effectiveness of BRCA mutation testing in breast cancer and on the use of radiotherapy in ductal carcinoma in situ of the breast are currently ongoing.

At the moment, the Network for Outcomes Research is involved in two ongoing clinical SAKK trials:

In a health economic subproject of trial **SAKK 96/12** (prevention of symptomatic skeletal events with denosumab administered every 4 weeks versus every 12 weeks), inpatient and outpatient costs are collected from hospitals using specific resource use forms and quality-adjusted life years are estimated within the trial using EQ-5D forms. The trial was reopened in 2021 and a grant application for the health economic analysis of the collected data is planned for 2023 or 2024.

Additionally, accrual for the cost analysis has been completed in the **SAKK 80/19 AlpineTIR** immunotherapy registry. Health economic data analysis is planned for 2024/25 with a focus on direct drug costs.

## Network for Cancer Predisposition Testing and Counseling

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### President

**Prof. Dr. med. Sheila Unger**

Lausanne University Hospital (CHUV)

### Vice president

**Dr. med. Salome Riniker**

Tumor- und BrustZentrum Ostschweiz TBZO

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The membership of the Section Network for Cancer Predisposition Testing and Counseling (CPTC) has dramatically increased in the last five years and 2022 was no exception. The CPTC now counts 146 active members from all regions of Switzerland. This reflects an ongoing need for medical professionals who can give adequate genetic counseling and who have the capacity to interpret genetic test results.

As with all fields of medicine, the CPTC has significant interactions with insurance companies and attends regular meetings with a committee representing the insurance doctors association. The reimbursement of genetic testing in the context of targeted therapies is especially important to CPTC members and their patients.

Our annual educational session was once again a huge success. We had the good fortune of hearing Dr. med. Matthias Kloor speak about his groundbreaking and highly innovative work on the development of a vaccine for Lynch syndrome. Preventive medicine would be a significant achievement for families faced with a genetic predisposition to cancer.

Prof. Dr. med. Sheila Unger resigned as CPTC president after serving a six-year term. Three highly qualified candidates ran for the presidency and Dr. med. Manuela Rabaglio was elected by a clear majority. Dr. med. Salome Riniker will remain in her position as vice president to ensure a smooth transition and to help manage the many key projects of the CPTC.

## Pathology

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### President

**Dr. med. Anne-Laure Rougemont**

Geneva University Hospitals (HUG)

### Co-author

**Prof. Dr. med. Chantal Pauli** University Hospital Zurich

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The Section Pathology can provide expertise in tissue selection and validation, morphological characterization, and molecular analysis.

Its ability to perform high-quality, accredited molecular analyses and interpret the results obtained identify the Section Pathology as a partner in the performance of clinical and translational studies. The section addresses quality assurance issues, with particular focus on pre-analytical and analytical tissue quality, on tumor content, etc., and on compliance with analytical standards.

Translational studies need to be planned ahead, and the Section Pathology aims to provide a central review of the quality and quantity of the pathology samples.

Translational research projects led by Pathology are also being initiated in collaboration with SAKK project and working groups. Prof. Dr. med. Rupert Langer, director of Pathology and Molecular Pathology at Johannes Kepler University and Kepler University Hospital in Linz, having previously worked at the University of Bern, has completed the first pathology-driven translational project associated with trial SAKK 75/08 (cetuximab in neoadjuvant therapy of esophageal cancer), and also led a study which has provided a comprehensive mutational analysis of esophageal carcinoma. An NGS study (Illumina TSO500 assay) was performed on tumor tissue (adenocarcinoma and squamous carcinoma) from 132 patients,

and the results were analyzed in correlation with clinical and pathological (TRG) parameters. The results were then compared with the TCGA data. This study also highlighted the need for complex biostatistics analysis.

Members of the Section Pathology wish to address specifically the archiving of residual material after trial completion and biobanking issues.

## Radio-Oncology

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### President

**Prof. Dr. med. Nicolaus Andratschke**

University Hospital Zurich

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### New president of Section Radio-Oncology

After eight years of active involvement in the Section Radio-Oncology, Prof. Dr. med. Frank Zimmermann opted to step down as president. The group is very grateful for his dedication and his achievements not only with regard to clinical trials but also to the standing of radiation oncology.

Prof. Dr. med. Nicolaus Andratschke has been nominated and elected as the new Section president. He is currently deputy chairman of the Department of Radiation Oncology at University Hospital Zurich and over the past decade he has been involved in clinical trials management at EORTC as responsible clinical RTQA chair and at SAKK as a member of the Section Radio-Oncology, the Project Group Lung Cancer, and the Working Group CNS Tumors.

### Active trials with successful recruitment

Dr. med. Alexandros Papachristofilou (University Hospital Basel) is the principal investigator of the recently published seminoma trial SAKK 01/10 and of the follow-up trial **SAKK 01/18**, which is investigating dose-reduced chemotherapy and radiotherapy in stage IIA/B seminoma. This trial is currently active and experiencing very high recruitment, and so it is considered to be a success.

In locally advanced, resectable stage III(N2) non-small cell lung cancer (NSCLC), trial **SAKK 16/18** investigates the immune-modulatory effect of stereotactic radiotherapy directed to the primary tumor only in addition to neoadjuvant chemo-immune therapy. Trial accrual has been

slower than expected, probably due to an overly optimistic estimation and the dip as a result of the COVID-19 pandemic. This pivotal trial nevertheless benefits from the full support of the section, and the participating members have been reminded of the importance of continuing to screen and recruit patients.

### New and upcoming trials and concepts in discussion

PD Dr. med. Panagiotis Balermipas (University Hospital Zurich) has successfully established the collaborative trial **“EORTC 2014 HNCG PROLoNg** trial: pembrolizumab and radiotherapy for oligometastatic squamous cell carcinoma of the head and neck, a randomized phase III trial”. With funding secured and the support of the SAKK established, including full endorsement by the Working Group Head and Neck Cancer and the Section Radio-Oncology, the trial is ready to be initiated and launched with eight sites to be opened in Switzerland.

Prof. Dr. med. Nicolaus Andratschke (University Hospital Zurich) is one of the coordinators of the **EORTC/ESTRO E2-Radiate ReCare** cohort, a prospective observational registry on patients receiving a second course of high-dose irradiation in a previously treated area. Currently, only two Swiss sites are intended to be opened for trial recruitment by EORTC, and this would represent an opportunity for SAKK to support additional high-recruiting sites in participating in this cohort.

New trials are being discussed and further developed within the section:

**“Rechallenge:** Repeat stereotactic radiotherapy for patients with CNS brain metastases” proposed by Dr. med. Brigitta Baumert (Cantonal Hospital Graubünden). This proposal primarily focuses on Type I re-irradiation of brain metastases and would favor a randomized approach.

**“TOTAL HYPO** trial: hypofractionated radiotherapy on pelvic nodes and prostate, delivered with a Simultaneous Integrated Boost technique, for non-metastatic unfavorable-intermediate or high-risk prostate cancer” proposed by Dr. med. Berardino de Bari (Réseau Hospitalier Neuchâtelois). This trial will be further developed together with the PG UG as it represents an opportunity for an innovative trial in prostate cancer. It would nevertheless still benefit from a better distinction from the Canadian HOPE trial.

## Registries

### President

PD Dr. med. Ulf Petrausch OnkoZentrum Zürich

### Vice president

Dr. med. Petros Tsantoulis

Geneva University Hospitals (HUG)

Multiple high-impact papers were published in 2022 using real-world data from clinical practice (see list below). This underlines the importance of the timely constitution of the Oncology Data Team at SAKK. At the semi-annual meeting, eight experts were elected to guide and develop SAKK's endeavor of collecting and analyzing clinical real-world data in order to better understand and teach modern oncology in Switzerland.

During the meeting we reported on the ongoing analysis of the **AlpineTIR registry**. Our data summarize published trials for patients with metastatic NSCLC, showing comparable outcomes (figure 1). This encourages the development of registries, which are high-quality, low-cost sources of clinical evidence.

We developed a scoring system to enable the Scientific Committee to evaluate, judge, and decide on registry proposals. Additionally, we created a hierarchy of SAKK support schemes for new registries. The aim is to allow more customized planning and execution of registries that meet the requirements, especially financial, of different research proposals (figure 2). However, all registry-supported schemes rely on the same data definitions, syntax, and data collection parameters, making it possible to exchange, compare and combine data from different registries.



We have also encountered certain obstacles. Convincing Ethics Committees of the value of registry projects and responding to valid concerns about privacy and data safety remain challenging. However, we are confident that scientific and methodological innovations, and a change in societal perspective, will help address these concerns to bring data analysis forward. From our perspective, data research is of key interest to SAKK, its members and—most importantly—cancer patients.

As the president of the group, I would like to thank every single member of the Oncology Data Team for their contribution, knowledge, and time (Jens Schulenburg, Head of Clinical Data Management, SAKK Competence Center; Dr. Stefanie Hayoz, Head of Statistics, SAKK Competence Center; Dr. med. Petros Tsantoulis, vice president, Section Registries; Prof. Dr. med. Chantal Pauli, representative, Scientific Committee; Dr. Daniel Hugelshofer, SCORED Project Manager, SAKK Competence Center; PDDr. med. Michael Mark, Cantonal Hospital Graubünden; Dr. med. Benjamin Kasenda, University Hospital Basel).

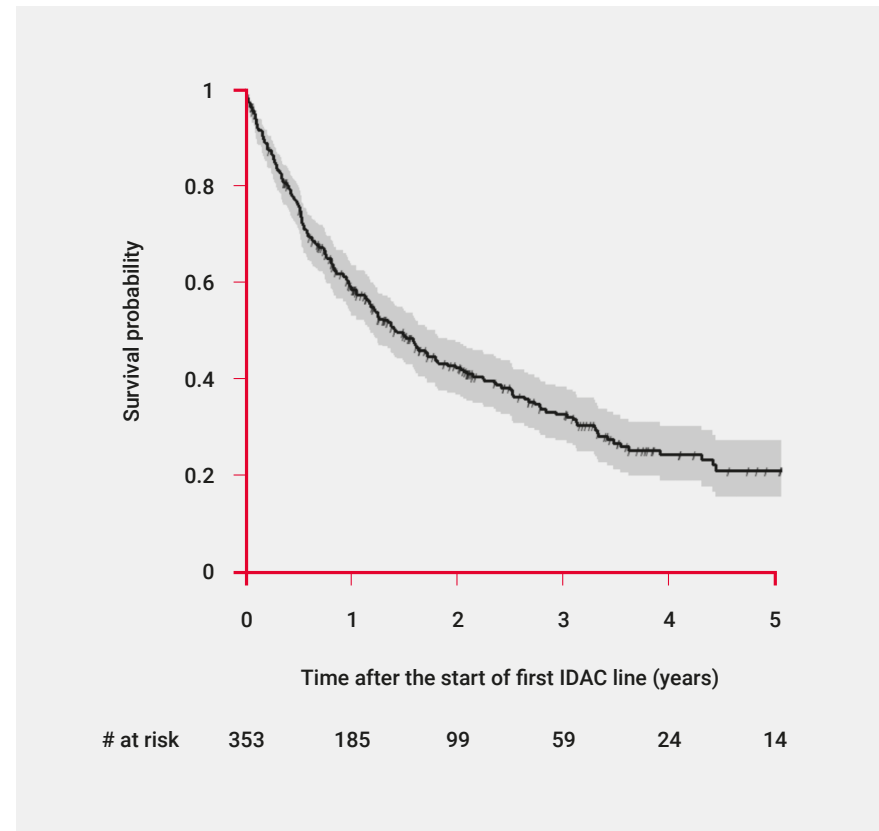
*A real-world comparison of tisagenlecleucel and axicabtagene ciloleucel CAR T-cells in relapsed or refractory diffuse large B cell lymphoma.* Bachy E., et al., *Nat Med.* 2022 Oct;28(10):2145-2154.

*Systematic pan-cancer analysis of mutation-treatment interactions using large real-world clinicogenomics data.* Liu R., et al., *Nat Med.* 2022 Aug;28(8):1656-1661.

*Comparing Trial and Real-world Adjuvant Oxaliplatin Delivery in Patients With Stage III Colon Cancer Using a Longitudinal Cumulative Dose.* Webster-Clark M., et al., *JAMA Oncol.* 2022 Oct 13:e 2022.4445

**Figure 1**

Overall survival in lung cancer patients after start of first IDAC line. IDAC = immune-modulating drug against cancer (checkpoint blocker)



**Figure 2**

Overview of the cost framework and different service levels provided by the Competence Center for registry implementation

<b>Benefits/services provided by the SAKK Competence Center</b>	<b>SAKK "label" kCHF 10–100</b>	<b>SAKK is sponsor kCHF 100–300</b>	<b>SAKK SCORED kCHF 300–600</b>
Core Data Set (CDS)			✓
3-year follow-up in 95% of patients			✓
Regular customized reports (aggregated data)			✓
General project management and documents		✓	✓
Legal/regulatory affairs, quality assurance		✓	✓
Data management and cleansing	(✓)	✓	✓
Statistical analysis	(✓)	✓	✓
Assistance with publication	(✓)	✓	✓
Use of CDS entities and semantics	✓	✓	✓
eCRF development, database maintenance	✓	✓	✓
PISIC and translations	✓	✓	✓

Excludes treatment sites and costs incurred outside the Competence Center SAKK consulting services may include all observation study components listed here.



Our Competence Center

# Trial Activities



“ It is gratifying that we were able to recruit more patients despite having fewer open trials.

**Christine Biaggi Rudolf**, Chief Operations Officer

**New organizational structure implemented:  
Clinical Operations / Clinical Science**

Clinical Trial Management, the biggest department at the SAKK Competence Center, was divided into two departments, Clinical Science (ClinSci) and Clinical Operations (ClinOps), effective January 1, 2022. This realignment will enable us to provide even more effective and professional support for all stakeholders.

In operational terms, ClinSci is primarily responsible for promoting the development of new ideas for trials and secondarily for drawing up trial protocols, while ClinOps deals with all operational activities through to termination once trials have been approved by the authorities and activated at the sites. 2022 was dominated by the process of defining and optimizing the new interfaces and these activities are set to continue throughout 2023.

**Trial and Patient Figures**

Trial activities in ClinOps during 2022 were at roughly the same level as previous years. Since there were not many new trials to open (three in total), we took the opportunity to conclude old trials that were ready for finalization.

We accrued a total of 576 patients in the 30 open trials being conducted through SAKK (including retrospective trials and registries). The vast majority of these (560 patients) were enrolled in prospective trials. It is gratifying that we were able to recruit more patients than in 2022 (576 vs. 540) despite having fewer open trials (30 vs. 33). We expect this trend to continue in 2023 since there has been a strong upturn in activity in the research groups.

# Quality Assurance and Compliance



“ The entirely positive result of this inspection is confirmation of the high quality standard to which SAKK clinical trials are performed.

**Céline Hummel** Chief Quality & Compliance Officer

## **Successful Swissmedic inspection**

In 2022, the SAKK Competence Center underwent its fourth routine GCP system inspection by Swissmedic following inspections in 2011, 2014 and 2017. The inspection focused on processes associated with the management of clinical trials, and particularly phase I trial SAKK 67/20. The entirely positive result of this inspection is confirmation of the high quality standard to which SAKK clinical trials are performed. We can particularly emphasize that we already have good processes in place for phase I trials and intend to continue to improve them going forward.

## **Submission processes optimized**

Once again, cooperation with the Ethics Committees, Swissethics and Swissmedic was very good in 2022. We held various constructive discussions with representatives of the Ethics Committees and Swissethics, which resulted in further optimization of our submission processes. The fact that we are now able to make almost entirely paper-free submissions to Swissmedic has also made processes more efficient at our end.

## **New data protection laws**

Following implementation of the new EU General Data Protection Regulation (GDPR), SAKK is required to appoint an independent data protection officer (DPO) so that it can continue to conduct SAKK trials in the EU. We were able to recruit a highly experienced and professional DPO

# Patient Numbers

## Patient recruitment

	2021	2022
<b>Total patients</b>	<b>540</b>	<b>576</b>
– from Switzerland	506	552
– from foreign countries	34	24
– in SAKK trials	394	268
– in trials with other cooperative groups/partners	146	308
– in clinical trials	357	560
– in retrospective trials, cohort trials, biobanks and registries	183	16
<b>Trials open for patient recruitment</b>	<b>33</b>	<b>30</b>
– SAKK trials	14	11
– Trials with other cooperative groups/partners	19	19

for SAKK during 2022 in the form of Dr. Sebastian Kraska of IITR Datenschutz GmbH. Cooperation with Dr. Kraska has already proven effective, interesting and instructive.

Switzerland’s revised Data Protection Act is now due to come into force in September 2023, following a slight delay. Our Legal Counsel, Johanna Böhlen, successfully completed a CAS (Certificate of Advanced Studies) on the subject during the year and has now assumed the role of primary point of contact for data protection issues within SAKK. In addition, we were able to recruit a highly experienced data protection consultant in the form of Dr. iur. Michèle Balthasar from Balthasar Legal AG, who will support and advise SAKK on all further data protection-related issues. We have thus completed the groundwork that will enable us to comply appropriately with the revised Data Protection Act.



## Patient Numbers Per Disease and Member

Member	Sites	Breast Cancer	Developmental Therapeutics	Gynecological Cancer	Leukemia	Lung Cancer	Lymphoma	Urogenital Tumors	Total
Aarau	Cantonal Hospital Aarau	8	0	0	5	2	0	0	15
Baden	Cantonal Hospital Baden	13	0	2	3	1	3	1	23
Basel	Bethesda Spital Brustzentrum Basel – Praxis Thorn Caba Zentrum für Onkologie, Psychologie und Bewegung Gesundheitszentrum Fricktal Cantonal Hospital Baselland Bruderholz Cantonal Hospital Baselland Liestal Onkopraxis Dr. med. A. Dieterle University Hospital Basel	33	0	2	7	9	0	5	56
Bern	University Hospital of Bern Lindenhofgruppe – Engeriedspital Lindenhofgruppe – Sonnenhofspital	5	2	0	12	5	6	2	32
Biel	Spitalzentrum Biel	0	0	0	0	0	0	0	0
Central Switzerland	Cantonal Hospital Lucerne (LUKS)	12	0	2	6	0	2	3	25
Claraspital	Claraspital	2	0	0	0	0	0	5	7
Fribourg	Centre du sein Fribourg/Brustzentrum Freiburg Hôpital Daler Cantonal Hospital Fribourg HFR	10	0	0	1	3	2	1	17
Geneva	Clinique des Grangettes Geneva University Hospitals (HUG) Praxis Dr. med. E. Tullen Praxis Dr. med. A. Hügli	10	3	0	1	15	3	0	32

Member	Sites	Breast Cancer	Developmental Therapeutics	Gynecological Cancer	Leukemia	Lung Cancer	Lymphoma	Urogenital Tumors	Total
Graubünden	Cantonal Hospital Graubünden Tumor- und BrustZentrum Ostschweiz Chur	11	7	2	3	6	8	5	<b>42</b>
Hirslanden	Brustzentrum (Seefeld) Brustzentrum Bern Biel Brustzentrum Ostschweiz Hirslanden Klinik Im Park Hirslandenklinik Aarau Hirslandenklinik Andreasklinik Cham Zug Hirslandenklinik St. Anna Klinik für Hämatologie und Onkologie Hirslanden Zürich AG Onkozentrum Zürich Tumorzentrum Aarau – Hirslanden TZA	54	0	0	0	0	4	2	<b>60</b>
Neuchâtel	Hôpital neuchâtelois – La Chaux-de-Fonds* Hôpital neuchâtelois – Neuchâtel* Réseau hospitalier neuchâtelois*	0	0	0	0	0	1	0	<b>1</b>
Solothurn	Bürgerspital Solothurn – Solothurner Spitäler Cantonal Hospital Olten – Solothurner Spitäler	4	0	0	0	0	2	0	<b>6</b>
St.Gallen	Cantonal Hospital St.Gallen Rundum Onkologie am Bahnhofpark Tumor- und BrustZentrum Ostschweiz Tumor- und BrustZentrum Ostschweiz Rapperswil	9	9	1	8	11	15	9	<b>62</b>
Thun	Radio-Onkologie Berner Oberland AG Spital STS AG Thun	0	0	0	2	0	0	0	<b>2</b>
Thurgau	Network – Spital Thurgau Spital Thurgau – Cantonal Hospital Frauenfeld Spital Thurgau – Cantonal Hospital Münsterlingen	14	0	1	3	0	0	4	<b>22</b>

Members	Sites	Breast Cancer	Developmental Therapeutics	Gynecological Cancer	Leukemia	Lung Cancer	Lymphoma	Urogenital Tumors	Total
Ticino	Clinica Luganese EOC – Oncology Institute of Southern Switzerland Fondazione Oncologia Lago Maggiore Oncologia Varini & Calderoni	6	3	0	7	6	3	2	27
Valais	Hôpital du Valais, Hôpital de Sion Hôpital du Valais, Spital Brig Network – Hôpitaux du Valais	15	0	0	2	0	0	2	19
Vaud	CCAC – Centre de Chimiothérapie Anti-Cancéreuse Lausanne University Hospital (CHUV) Clinique de Genolier	14	0	0	2	0	1	4	21
Winterthur	Cantonal Hospital Winterthur	25	0	0	7	4	3	2	41
Zurich	Onkologie Bellevue Brustzentrum Spital Zollikerberg	5	0	0	0	0	0	0	5
Zurich Triemli	Spital Limmattal Stadtspital Triemli Stadtspital Waid	7	0	0	0	0	1	3	11
Zurich USZ	Spital Männedorf University Hospital Zurich	2	1	0	7	8	4	4	26
Total Foreign Countries		0	0	0	0	0	2	22	24
<b>Total</b>		<b>259</b>	<b>25</b>	<b>10</b>	<b>76</b>	<b>70</b>	<b>60</b>	<b>76</b>	<b>576</b>

\* Réseau hospitalier neuchâtelois became an SAKK member on November 15, 2022. It was previously part of the Fribourg member. Here the accrual is split between the two members based on the registration date.

# Conducted Trials 2022

## Activated trials

Disease group	Trial name	Trial title	Coordinating investigator	Activation
<b>Breast Cancer</b>	DECRESCENDO	De-Escalation of adjuvant ChemotheRapy in HER2-positive, EStrogen reCEptor-negative, Node-negative early breast cancer patients who achieved pathological complete response after neoadjuvant chemotherapy and Dual HER2 bLockade	Andreas Müller	11.30.2022
<b>Developmental Therapeutics</b>	IP-IIO-622_ SAKK 69/22	Intratumoral injection of IP-001 following thermal ablation in patients with advanced solid tumors. A multicenter Phase 1b/2a trial in colorectal cancer, non-small cell lung cancer, and soft tissue sarcoma patients	Markus Jörger	11.08.2022
<b>Urogenital Tumors</b>	SAKK 06/19	Intravesical recombinant BCG followed by perioperative chemo-immunotherapy for patients with muscle-invasive bladder cancer (MIBC). A multicenter, single-arm phase II trial.	Richard Cathomas	04.27.2022

# Open Trials

Disease group	Trial name	Trial title	Coordinating investigator	Activation
<b>Breast Cancer</b>	DECRESCENDO	De-Escalation of adjuvant ChemotheRapy in HER2-positive, EStrogen reCEptor-negative, Node-negative early breast cancer patients who achieved pathological complete response after neoadjuvant chemotherapy and Dual HER2 bIockade	Andreas Müller	11.30.2022
	IBCSG 55-17 TOUCH	Phase II open-label, multicenter, randomized trial of neoadjuvant palbociclib in combination with hormonal therapy and HER2 blockade versus paclitaxel in combination with HER2 blockade for elderly patients with hormone receptor positive/HER2 positive early breast cancer	Patrik Weder	10.30.2018
	IBCSG 59-19 POLAR	A phase III open-label, multicenter, randomized trial of adjuvant palbociclib in combination with endocrine therapy versus endocrine therapy alone for patients with hormone receptor positive / HER2-negative resected isolated locoregional recurrence of breast cancer	Stefan Paul Aebi	08.27.2019
	SAKK 23/16	Tailored AXillary Surgery with or without axillary lymph node dissection followed by radiotherapy in patients with clinically node-positive breast cancer (TAXIS). A multicenter randomized open labeled phase III trial.	Walter Weber	07.31.2018
	SAKK 23/18	Vacuum assisted biopsy Immediately before Surgery as an Intra- or pre-Operative surrogate for patient response to Neoadjuvant chemotherapy for breast cancer (VISION I)	Christoph Tausch	06.30.2020
<b>Developmental Therapeutics</b>	BASILEA CDI-CS-002	An open-label Phase 1/2a study of oral BAL101553 in adult patients with advanced solid tumors and in adult patients with recurrent or progressive glioblastoma or high-grade glioma	Thomas Hundsberger	02.15.2021
	BAY 1895344	A multicenter, non-randomized, open-label phase 1b study to determine the maximum tolerated and recommended phase 2 dose of the ATR Inhibitor BAY 1895344 in combination with pembrolizumab and to characterize its safety, tolerability, pharmacokinetics and preliminary anti-tumor activity in patients with advanced solid tumors	Markus Jörger	04.14.2021
	IP-IIO-622_ SAKK 69/22	Intratumoral injection of IP-001 following thermal ablation in patients with advanced solid tumors. A multicenter Phase 1b/2a trial in colorectal cancer, non-small cell lung cancer, and soft tissue sarcoma patients	Markus Jörger	11.08.2022
	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	06.27.2017
	SAKK 65/16	TLD-1, a novel liposomal doxorubicin, in patients with advanced solid tumors. A multicenter open-label single-arm phase I trial.	Dagmar Hess	10.26.2018

<b>Disease group</b>	<b>Trial name</b>	<b>Trial title</b>	<b>Coordinating investigator</b>	<b>Activation</b>
<b>Developmental Therapeutics</b>	SAKK 66/17	Intratumoral injection of IP-001 following thermal ablation in patients with advanced solid tumors. A multicenter phase Ib/IIa trial with expansion cohorts in melanoma and soft tissue sarcoma patients	Markus Jörger	07.02.2020
	SAKK 67/20	Open-label dose escalation phase 1b trial of a new micellar docetaxel compound in patients with metastatic castration-resistant prostate cancer	Ilaria Colombo	05.28.2021
	SAKK 69/17	Open-label, FIH dose-escalation study to evaluate the safety, tolerability, PK, PD, MTD or optimum biologic dose of the ATR inhibitor BAY 1895344 in patients with advanced solid tumors and lymphomas	Markus Jörger	05.25.2021
<b>Gynecological Cancer</b>	AGO-OVAR	Atezolizumab in combination with Bevacizumab +/- Chemotherapy versus Chemo-Bevacizumab standard in recurrent ovarian cancer – a randomised Phase III trial	Christian Kurzeder	03.04.2021
<b>Leukemia</b>	CLL 17	A phase 3 multicenter, randomized, prospective, open-label trial of ibrutinib mono-therapy versus fixed-duration venetoclax plus obinutuzumab versus fixed-duration ibrutinib plus venetoclax in patients with previously untreated chronic lymphocytic leukemia (CLL)	Michael Gregor	12.16.2021
	HOVON 150	A phase 3, multicenter, double-blind, randomized, placebo-controlled study of ivosidenib or enasidenib in combination with induction therapy and consolidation therapy followed by maintenance therapy in patients with newly diagnosed acute myeloid leukemia or myelodysplastic syndrome with excess blasts-2, with an IDH1 or IDH2 mutation, eligible for intensive chemotherapy	Markus G. Manz	12.05.2019
	HOVON 156	HOVON 156 / AMLSG 28-18: A phase 3, multicenter, open-label, randomized, study of Gilteritinib versus Midostaurin in combination with induction and consolidation therapy followed by one-year maintenance in patients with newly diagnosed acute myeloid leukemia (AML) or myelodysplastic syndromes with excess blasts-2 (MDS-EB2) with FLT3 mutations eligible for intensive chemotherapy	Thomas Pabst	10.15.2020
<b>Lung Cancer</b>	ETOP BEAT-meso	A multicentre randomised phase III trial comparing atezolizumab plus bevacizumab and standard chemotherapy versus bevacizumab and standard chemotherapy as first-line treatment in advanced malignant pleural mesothelioma	Amina Scherz	06.06.2019
	ETOP CHESS	A multicentre single arm phase II trial assessing the efficacy of radical immunotherapy and chemotherapy, stereotactic radiotherapy and surgery in patients with synchronous oligo-metastatic NSCLC	Rolf A. Stahel	10.10.2019
	SAKK 15/19	Thoracic radiotherapy plus maintenance Durvalumab after first line Carboplatin and Etoposide plus Durvalumab in extensive-stage disease small cell lung cancer (ED-SCLC) A multicenter single arm open label phase II trial	Alfredo Addeo	06.24.2021



<b>Disease group</b>	<b>Trial name</b>	<b>Trial title</b>	<b>Coordinating investigator</b>	<b>Activation</b>
<b>Lung Cancer</b>	SAKK 16/18	Immune-modulatory radiotherapy to enhance the effects of neoadjuvant PD-L1 blockade and neoadjuvant chemotherapy in patients with stage III(N2) non-small cell lung cancer (NSCLC). A multicenter single-arm phase II trial.	Laetitia Mauti	04.28.2020
	SAKK 17/18	Overcoming Resistance to Immunotherapy combining Gemcitabine with atezolizumab in advanced NSCLC and mesothelioma progressing under immune-checkpoint inhibitors or gemcitabine. A multicenter, single-arm, open label phase II trial with two cohorts.	Alessandra Curioni-Fontecedro	03.02.2021
	SAKK 19/17	First line durvalumab in patients with PD-L1 positive, advanced NSCLC with performance status 2 unsuitable for combination chemotherapy. A multicenter, single-arm phase II trial	Michael Thomas Mark	10.23.2018
<b>Lymphoma</b>	EMCL-Registry	The Registry of the European Mantle Cell Lymphoma study group	Martin Fehr	12.20.2019
	HD 21	HD21 for advanced stages: Treatment optimization trial in the first-line treatment of advanced stage Hodgkin lymphoma; comparison of 4-6 cycles of escalated BEACOPP with 4-6 cycles of BrECADD	Alden Moccia	05.29.2017
	IELSG-47	Phase II study of combination ibrutinib and rituximab in untreated marginal zone lymphomas	Emanuele Zucca	02.13.2020
	SAKK 38/19	Assessing a ctDNA and PET-oriented therapy in patients with DLBCL. A multicenter, open-label, phase II trial	Anastasios Stathis	06.08.2021
<b>Urogenital Tumors</b>	SAKK 01/18	Reduced intensity radiochemotherapy for Stage IIA/B Seminoma. A multicenter, open label phase II trial with two cohorts	Alexandros Papachristoflou	07.11.2019
	SAKK 06/19	Intravesical recombinant BCG followed by perioperative chemo-immunotherapy for patients with muscle-invasive bladder cancer (MIBC). A multicenter, single-arm phase II trial.	Richard Cathomas	04.27.2022
	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	07.16.2014

## Closed Trials

Disease group	Trial name	Trial title	Coordinating investigator	Closed
<b>Breast Cancer</b>	IBCSG 55-17 TOUCH	Phase II open-label, multicenter, randomized trial of neoadjuvant palbociclib in combination with hormonal therapy and HER2 blockade versus paclitaxel in combination with HER2 blockade for elderly patients with hormone receptor positive/HER2 positive early breast cancer	Patrik Weder	08.03.2022
<b>Developmental Therapeutics</b>	BASILEA CDI-CS-002	An open-label Phase 1/2a study of oral BAL101553in adult patients with advanced solid tumors and in adult patients with recurrent or progressive glioblastoma or high-grade glioma	Thomas Hundsberger	07.31.2022
	BAY 1895344	A multicenter, non-randomized, open-label phase 1b study to determine the maximum tolerated and recommended phase 2 dose of the ATR Inhibitor BAY 1895344 in combination with pembrolizumab and to characterize its safety, tolerability, pharmacokinetics and preliminary anti-tumor activity in patients with advanced solid tumors	Markus Jörger	08.01.2022
<b>Gynecological Cancer</b>	AGO-OVAR	Atezolizumab in combination with Bevacizumab +/- Chemotherapy versus Chemo-Bevacizumab standard in recurrent ovarian cancer – a randomised Phase III trial	Christian Kurzeder	07.13.2022
<b>Leukemia</b>	CLL 17	A phase 3 multicenter, randomized, prospective, open-label trial of ibrutinib mono-therapy versus fixed-duration venetoclax plus obinutuzumab versus fixed-duration ibrutinib plus venetoclax in patients with previously untreated chronic lymphocytic leukemia (CLL)	Michael Gregor	11.17.2022
<b>Lung Cancer</b>	ETOP BEAT-meso	A multicentre randomised phase III trial comparing atezolizumab plus bevacizumab and standard chemotherapy versus bevacizumab and standard chemotherapy as first-line treatment in advanced malignant pleural mesothelioma	Amina Scherz	03.07.2022
	SAKK 17/18	Overcoming Resistance to Immunotherapy combining Gemcitabine with atezolizumab in advanced NSCLC and mesothelioma progressing under immune-checkpoint inhibitors or gemcitabine. A multicenter, single-arm, open label phase II trial with two cohorts.	Alessandra Curioni-Fontecedro	06.13.2022
	SAKK 19/17	First line durvalumab in patients with PD-L1 positive, advanced NSCLC with performance status 2 unsuitable for combination chemotherapy. A multicenter, single-arm phase II trial	Michael Thomas Mark	04.07.2022
<b>Lymphoma</b>	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	03.29.2022
	IELSG-47	Phase II study of combination ibrutinib and rituximab in untreated marginal zone lymphomas	Emanuele Zucca	04.11.2022

# Our Trial Results



# Trial Results and Presentations



“ It makes me proud that we were able to publish the results of an SAKK trial in such a prestigious journal.

**Dr. Stefanie Hayoz** Head of Statistics

## **Scientific publications**

Last year, 34 articles involving SAKK appeared in various scientific journals. I would particularly like to point out the article on trial SAKK 01/10, which appeared in *The Lancet Oncology*. This trial, run by SAKK in collaboration with the interdisciplinary German Testicular Cancer Study Group (GTCSG), is the largest completed prospective study on treatment optimization in stage IIA/B seminoma and has shown very promising and potentially practice-changing results. It makes me proud that we were able to publish the results of an SAKK trial in such a prestigious journal.

## **SAKK presence at oncology congresses**

SAKK was well represented both at the major oncology congresses and at more local events with 16 posters and 19 oral presentations.

SAKK contributed two oral presentations and three posters at the American Society of Clinical Oncology (ASCO) annual meeting, as well as two posters and two oral presentations at the European Society for Medical Oncology (ESMO) congress.

## **Consulting services**

As part of our statistical advisory work, we were able to assist with around 18 non-SAKK projects of varying sizes and contribute to presentations and manuscripts.

## **Reports on clinical trials**

The statistics team produced 13 clinical trial reports for SAKK trials, including 8 final reports for the authorities.

## Publications by SAKK and Cooperative Groups 2022

Cancer type	Trial	Title	Authors	Journal	Impact factor
Breast Cancer	IBCSG 24-02	Adjuvant Endocrine Therapy in Premenopausal Breast Cancer: 12-Year Results From SOFT	Francis PA, Fleming GF, Láng I, Ciruelos EM, Bonnefoi HR, Bellet M, Bernardo A, Climent MA, Martino S, Bermejo B, Burstein HJ, Davidson NE, Geyer CE Jr, Walley BA, Ingle JN, Coleman RE, Müller B, Le Du F, Loibl S, Winer EP, Ruepp B, Loi S, Colleoni M, Coates AS, Gelber RD, Goldhirsch A, Regan MM, for the SOFT Investigators and the International Breast Cancer Study Group	J CLIN ONCOL	50.717
	IBCSG 24-02 (SOFT), IBCSG 25-02 (TEXT)	Adjuvant Exemestane With Ovarian Suppression in Premenopausal Breast Cancer: Long-Term Follow-Up of the Combined TEXT and SOFT Trials	Pagani O, Walley BA, Fleming GF, Colleoni M, Láng I, Gomez HL, Tondini C, Burstein HJ, Goetz MP, Ciruelos EM, Stearns V, Bonnefoi HR, Martino S, Geyer CE Jr, Chini C, Puglisi F, Spazzapan S, Ruhstaller T, Winer EP, Ruepp B, Loi S, Coates AS, Gelber RD, Goldhirsch A, Regan MM, Francis PA	J CLIN ONCOL	50.717
	IBCSG 24-02 (SOFT), IBCSG 25-02 (TEXT)	Aromatase inhibitors versus tamoxifen in premenopausal women with oestrogen receptor-positive early-stage breast cancer treated with ovarian suppression: a patient-level meta-analysis of 7030 women from four randomised trials	Bradley R, Braybrooke J, Gray R, Hills R, Liu Z, Pan H, Peto R, Dodwell D, McGale P, Taylor C, Bergh J, Swain S, Francis PA, Gnant M, Perrone F, Regan MM	LANCET ONCOL	41.316
	IBCSG 38-10	Radiation doses and fractionation schedules in non-low-risk ductal carcinoma in situ in the breast (BIG 3-07/TROG 07.01): a randomised, factorial, multicentre, open-label, phase 3 study	Chua BH, Link EK, Kunkler IH, Whelan TJ, Westenberg AH, Gruber G, Bryant G, Ahern V, Purohit K, Graham PH, Akra M, McArdle O, O'Brien P, Harvey JA, Kirkove C, Maduro JH, Campbell ID, Delaney GP, Martin JD, Vu T TT, Muanza TM, Neal A, Olivotto IA, BIG 3-07/TROG 07.01 trial investigators	LANCET	202.731
	IBCSG 40-11	Effect of Metformin vs Placebo on Invasive Disease-Free Survival in Patients With Breast Cancer: The MA.32 Randomized Clinical Trial	Goodwin PJ, Chen BE, Gelmon KA, Whelan TJ, Ennis M, Lemieux J, Ligibel JA, Hershman DL, Mayer IA, Hobday TJ, Bliss JM, Rastogi P, Rabaglio-Poretti M, Mukherjee SD, Mackey JR, Abramson VG, Oja C, Wesolowski R, Thompson AM, Rea DW, Stos PM, Shepherd LE, Stambolic V, Parulekar WR	JAMA	56.272

Cancer type	Trial	Title	Authors	Journal	Impact factor
<b>Breast Cancer</b>	SAKK 21/12	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	Vetter M, Rothgiesser KM, Qiyu L, Hawle H, Schönfeld W, Ribí K, Riniker S, von Moos R, Trojan A, Kralidis E, Fehr M, Müller A, Thuerlimann B	ENDOCRINE ONCOLOGY	N/A
	SAKK 25/14	Eribulin as first-line treatment in elderly patients (= 70 years) with advanced breast cancer: a multicenter Phase II trial [SAKK 25/14]	Hasler-Strub U, Mueller A, Li Q, Thuerlimann B, Ribí K, Gerber S, von Moos R, Fehr M, Rochlitz C, Zaman K, Aebi S, Hochstrasser A, Gick U, Baertschi D, Greuter S, Schreiber A, Caspar C, Trojan A, Condorelli R, Ruhstaller T	J GERIATR ONCOL	3.929
<b>Developmental Therapeutics</b>	SAKK 80/20_CaSA	Outcome and prognostic factors of COVID-19 infection in Swiss cancer patients: Final results of SAKK 80/20 (CaSA)	Joerger M, Metaxas Y, Zaman K, Michielin O, Mach N, Bettini A, Schmitt AM, Cantoni N, Caspar CB, Stettler S, Malval R, Pless M, Britschgi C, Renner C, Koeberle D, Schulz JD, Kopp C, Hayoz S, Stathis A, von Moos R	CANCERS	6.162
<b>Gastrointestinal Cancer</b>	SAKK 41/16	Population pharmacokinetic analyses of regorafenib and capecitabine in patients with locally advanced rectal cancer (SAKK 41/16 RECAP)	Schmulenson E, Bovet C, Theurillat R, Decosterd LA, Largiadèr CR, Prost JC, Csajka C, Bärtschi D, Guckenberger M, von Moos R, Bastian S, Joerger M, Jaehde U	BJCP	3.716
	SAKK 75/08	Patterns of care for relapsed oesophageal cancer after initial curative trimodality therapy: Long-term follow-up of the SAKK 75/08 trial	Panje C, Hayoz S, Eisterer W, Hess V, Thuss-Patience P, Schacher S, Dürr D, Wagner AD, Girschikofsky M, Eboulet E, Stahl M, Ruhstaller T	EUR J CANCER	9.162
<b>Leukemia</b>	HOVON 103 - SEL	Addition of the nuclear export inhibitor selinexor to standard intensive treatment for elderly patients with AML and high risk MDS	Janssen JJWM, Löwenberg B, Manz M, Biemond BJ, Westerweel PE, Klein SK, Fehr M, Sinnige HAM, Efthymiou A, Legdeur MCJC, Pabst T, Gregor M, van der Poel MWM, Deeren D, Tick LW, Jongen-Lavrencic M, van Obbergh F, Boersma RS, de Weerd O, Chalandon Y, Heim D, Spertini O, van Sluis G, Graux C, Stüssi G, van Norden Y, Ossenkoppele GJ	LEUKEMIA	11.528



Cancer type	Trial	Title	Authors	Journal	Impact factor
<b>Leukemia</b>	HOVON/SAKK 92, 102, 103 and 132	Concordance in Measurable Residual Disease result and outcome after first- and second induction cycle in Acute Myeloid Leukemia	Tettero JM, Al-Badri WKW, Ngai LL, Bachas C, Breems DA, van Elssen CHMJ, Fischer T, Gjertsen BT, van Gorkom GNY, Gradowska P, Greuter MJE, Griskevicius L, Juliusson G, Maertens J, Manz MG, Pabst T, Passweg J, Porkka K, Löwenberg B, Ossenkoppele GJ	FRONT ONCOL	6.244
<b>Lung Cancer</b>	ETOP ALERT	Alectinib for the treatment of pretreated RET-rearranged advanced NSCLC: Results of the ETOP ALERT-lung trial	Felip E, Smit EF, Molina-Vila MA, Dafni U, Massuti B, Berghmans T, de Marinis F, Passiglia F, Dingemans A-MC, Cobo M, Viteri S, Britschgi C, Cuffe S, Provencio M, Merkelbach-Bruse S, Andriakopoulou C, Kammler R, Ruepp B, Roschitzki-Voser H, Peters S, Wolf J, Stahel R.	LUNG CANCER	6.081
	ETOP BOOSTER	Impact of smoking status on the relative efficacy of the EGFR TKI/angiogenesis inhibitor combination therapy in advanced NSCLC – A systematic review and meta-analysis	Dafni U, Soo RA, Peters S, Tsourti Z, Zygoura P, Vervita K, Han JY, De Castro J, Coate L, Früh M, Hashemi SMS, Nadal E, Carcereny E, Sala MA, Bernabé R, Provencio M, Cuffe S, Roschitzki-Voser H, Ruepp B, Rosell R, Stahel RA	ESMO OPEN	6.540
	ETOP PROMISE-meso	A prognostic score for patients with malignant pleural mesothelioma (MPM) receiving second-line immunotherapy or chemotherapy in the ETOP 9 15 PROMISE-meso phase III trial	Banna G L, Addeo A, Zygoura P, Tsourti Z, Popat S, Curioni-Fontecedro A, Nadal E, Shah R, Pope A, Fisher P, Spicer J, Roy A, Gilligan D, Gautschi O, Janthur WD, López-Castro R, Roschitzki-Voser H, Dafni U, Peters S, Stahel RA	LUNG CANCER	5.705
	SAKK 19/18	Fibroblast growth factor receptor (FGFR) inhibitor rogaratinib in patients with advanced pretreated squamous-cell non-small cell lung cancer over-expressing FGFR mRNA: the SAKK 19/18 phase II study	Addeo A, Rothschild SI, Holer L, Schneider M, Waibel C, Haefliger S, Mark M, Fernandez E, Mach N, Mauti L, Jermann PM, Alborelli I, Calgua B, Savic-Prince S, Joerger M, Früh M	LUNG CANCER	6.081
	SAKK 16/14	Magnesium sensing via LFA-1 regulates CD8+ T cell effector function	Lötscher J, Martí I Líndez AA, Kirchhammer N, Cribioli E, Giordano Attianese GMP, Trefny MP, Lenz M, Rothschild SI, Strati P, Künzli M, Lotter C, Schenk SH, Dehio P, Löliger J, Litzler L, Schreiner D, Koch V, Page N, Lee D, Grählert J, Kuzmin D, Burgener AV, Merkler D, Pless M, Balmer ML, Reith W, Huwyler J, Irving M, King CG, Zippelius A, Hess C	CELL	41.582

Cancer type	Trial	Title	Authors	Journal	Impact factor
Lung Cancer	SAKK 16/96, 16/00, 16/01	Extended resection for potentially operable stage III NSCLC patients after neoadjuvant treatment	Furrer K, Weder W, Eboulet EI, Betticher D, Pless M, Stupp R, Krueger T, Perentes JY, Schmid RA, Lardinnois D, Furrer M, Früh M, Peters S, Curioni-Fontecedro A, Stahel RA, Rothschild SI, Hayoz S, Opitz I.	J THORAC CARDIOVASC SURG	5.209
	SAKK 16/96, 16/00, 16/01, 16/08	Long-term outcomes of operable stage III NSCLC in the pre-immunotherapy era. Results from a pooled analysis of the SAKK 16/96, SAKK 16/00, SAKK 16/01, and SAKK 16/08 trials	König D, Schär S, Vuong D, Guckenberger M, Furrer K, Opitz I, Weder W, Rothschild SI, Ochsenbein A, Zippelius A, Addeo A, Mark M, Eboulet EI, Hayoz S, Thierstein S, Betticher DC, Ris HB, Stupp R, Curioni-Fontecedro A, Peters S, Pless M, Früh M	ESMO OPEN	5.329
	SAKK 17/04	Viral mimicry response is associated with clinical outcome in pleural mesothelioma	Sun S, Qi W, Rehrauer H, Ronner M, Hariharan A, Wipplinger M, Meiller C, Stahel R, Früh M, Cercello F, Fonteneau JF, Jean D, Felley-Bosco E	JTO CLIN RES REP	N/A
	SAKK 17/16	Long term benefit of lurbinectedin as palliative chemotherapy in progressive malignant pleural mesothelioma (MPM): Follow-up efficacy and translational part of the SAKK 17/16 study	Mark M, Rusakiewicz S, Früh M, Hayoz S, Grosso F, Pless M, Zucali P, Ceresoli GL, Maconi A, Schneider M, Froesch P, Tarussio D, Benedetti F, Dagher J, Kandalaft L, von Moos R, Tissot-Renaud S, Schmid S, Metaxas Y	ESMO OPEN	5.329
Lymphoma	HD 16	Predictive value of baseline metabolic tumor volume in early-stage favorable Hodgkin Lymphoma - Data from the prospective, multicenter phase III HD16 trial	van Heek L, Stuka C, Kaul H, Müller H, Mettler J, Hitz F, Baues C, Fuchs M, Borchmann P, Engert A, Dietlein M, Voltin CA, Kobe C	BMC CANCER	4.638
	SAKK 35/15	SAKK 35/15: a phase 1 trial of obinutuzumab in combination with venetoclax in patients with previously untreated follicular lymphoma	Stathis A, Mey UJM, Schär S, Hitz F, Pott C, Mach N, Krasniqi F, Novak U, Schmidt C, Hohloch K, Kienle DL, Hess D, Moccia AA, Unterhalt M, Eckhardt K, Hayoz S, Forestieri G, Rossi D, Dirnhofer S, Ceriani L, Sartori G, Bertoni F, Buske C, Zucca E, Hiddemann W	BLOOD ADV	6.799
	SAKK 38/07	Integration of baseline metabolic parameters and mutational profile predict long-term response to first-line therapy in DLBCL patients. A post hoc analysis of SAKK38/07 study (18) F-fluorodeoxyglucose positron emission tomography (PET)/computed tomography (CT) parameters, combined with muta	Genta S, Ghilardi G, Cascione L, Juskevicius D, Tzankov A, Schär S, Milan L, Piroso MC, Esposito F, Ruberto T, Giovannella L, Hayoz S, Mamot C, Dirnhofer S, Zucca E, Ceriani L	CANCERS	6.639

Cancer type	Trial	Title	Authors	Journal	Impact factor
Urogenital Tumors	STAMPEDE	Abiraterone acetate plus prednisolone for metastatic patients starting hormone therapy: 5-year follow-up results from the STAMPEDE randomised trial (NCT00268476)	James ND, Clarke NW, Cook A, Ali A, Hoyle AP, Attard G, Brawley CD, Chowdhury S, Cross WR, Dearnaley DP, de Bono JS, Diaz-Montana C, Gilbert D, Gillessen S, Gilson C, Jones RJ, Langley RE, Malik ZI, Matheson DJ, Millman R, Parker CC, Pugh C, Rush H, Russell JM, Berthold DR, Buckner ML, Mason MD, Ritchie AWS, Birtle AJ, Brock SJ, Das P, Ford D, Gale J, Grant W, Gray EK, Hoskin P, Khan MM, Manetta C, McPhail NJ, O'Sullivan JM, Parikh O, Perna C, Pezaro CJ, Protheroe AS, Robinson AJ, Rudman SM, Sheehan DJ, Srihari NN, Syndikus I, Tanguay JS, Thomas CW, Vengalil S, Wagstaff J, Wylie JP, Parmar MKB, Sydes MR	INT J CANCER	7.316
	STAMPEDE	Docetaxel for Nonmetastatic Prostate Cancer: Long-Term Survival Outcomes in the STAMPEDE Randomized Controlled Trial	James ND, Ingleby FC, Clarke NW, Amos CL, Attard G, Brawley CD, Chowdhury S, Cross W, Dearnaley DP, Gilbert DC, Gillessen S, Jones RJ, Langley RE, Macnair A, Malik ZI, Mason MD, Matheson DJ, Millman R, Parker CC, Rush HL, Russell JM, Au C, Ritchie AWS, Mestre RP, Ahmed I, Birtle AJ, Brock SJ, Das P, Ford VA, Gray EK, Hughes RJ, Manetta CB, McLaren DB, Nikapota AD, O'Sullivan JM, Perna C, Peedell C, Protheroe AS, Sundar S, Tanguay JS, Tolan SP, Wagstaff J, Wallace JB, Wylie JP, Zarkar A, Parmar MKB, Sydes MR.	JNCI CANCER SPECTR	N/A
	SAKK 01/10	Single-dose carboplatin followed by involved-node radiotherapy for stage IIA/B seminoma: SAKK 01/10	Papachristofilou A, Bedke J, Hayoz S, Schratzenstaller U, Pless M, Hentrich M, Kregge S, Lorch A, Aebersold DM, Putora PM, Berthold DR, Zihler D, Zengerling F, Dieing A, Mueller AC, Schaer C, Biaggi C, Gillessen S, Cathomas R	LANCET ONCOL	54.433
	SAKK 06/14	Results of a phase II single arm clinical trial assessing efficacy, safety and tolerability of the recombinant Bacillus Calmette Guérin (rBCG) VPM1002BC in patients with high-grade non muscle-invasive bladder cancer recurrence after BCG induction with or without BCG maintenance therapy – SAKK 06/14	Rentsch CA, Thalmann GN, Lucca I, Kwiatkowski M, Wirth GJ, Strebel RT, Engeler D, Pedrazzini A, Hüttenbrink C, Schultze-Seemann W, Torpai R, Bubendorf L, Wicki A, Roth B, Bosshard P, Püschel H, Boll DT, Hefermehl L, Roghmann F, Gierth M, Ribi K, Schäfer S, Hayoz S	EUR UROL ONCOL	7.479

Cancer type	Trial	Title	Authors	Journal	Impact factor
<b>Urogenital Tumors</b>	SAKK 09/10	Adherence to contouring and treatment planning requirements within a multicentric trial -results of the quality assurance of the SAKK 09/10 trial	Beck M, Sassowsky M, Schär S, Mathier E, Halter M, Zwahlen DR, Hölscher T, Arnold W, Polat B, Hildebrandt G, Müller AC, Putora PM, Papachristofilou A, Hayoz S, Schär C, Li Q, Sumila M, Zaugg K, Guckenberger M, Ost P, Bosetti DG, Reuter C, Gomez S, Khanfir K, Aebersold DM, Ghadjar P, Pra AD	INT J RADIAT ONCOL BIOL PHYS	4.495
	SAKK 09/10	Validation of the Decipher Genomic Classifier in SAKK 09/10: A Phase 3 Randomized Trial of Dose-escalated Salvage Radiotherapy after Radical Prostatectomy	Dal Pra A, Ghadjar P, Hayoz S, Liu VYT, Spratt DE, Thompson DJS, Davicioni E, Huang HC, Zhao X, Liu Y, Schär C, Gut P, Plasswilm L, Hölscher T, Polat B, Hildebrandt G, Müller AC, Pollack A, Thalmann GN, Zwahlen D, Aebersold DM	ANN ONCOL	7.040
<b>Consulting</b>		The role of immune checkpoint inhibitors in clinical practice: an analysis of the treatment patterns, survival and toxicity rates by sex	Wahli MN, Hayoz S, Hoch D, Ryser CO, Hoffmann M, Scherz A, Schwacha-Eipper B, Häfliger S, Wampfler J, Berger MD, Novak U, Özdemir BC	J CANCER RES CLIN ONCOL	4.322
		Prognostic relevance of mixed histological subtypes in invasive breast carcinoma: a retrospective analysis	Rechsteiner A, Dietrich D, Varga Z	J CANCER RES CLIN ONCOL	4.322
		Prescription patterns, recurrence and toxicity rates of adjuvant treatment for stage III/IV melanoma- A real world single-centre analysis	Hoffmann M, Hayoz S, Özdemir B C	BIOLOGY	5.007
		Prediction of Biochemical Recurrence Based on Molecular Detection of Lymph Node Metastasis After Radical Prostatectomy	Oezdemir BC, Arnold N, Fleischmann A, Hensel J, Klima I, Kruithof-de Julio M, Burkhard F, Hayoz S, Kiss B, Thalmann GM	EUR UROL OPEN SCI	3.000

## Presentations on SAKK and Cooperative Group Trials 2022

Conference	Abstract	Trial	Title	Authors
ASCO	Oral presentation	IBCSG 24-02 (SOFT), IBCSG 25-02 (TEXT)	Historical early treatment effects of adjuvant endocrine therapy for breast cancer in high-risk subgroups: Reanalysis of BIG 1-98, SOFT and TEXT.	Regan MM, Niman SM, Fleming GF, Walley B, Viale G, Thurlimann BJK, Loi S, Colleoni M, Pagani O, Francis PA
	Poster	SAKK 65/16	TLD-1, a novel liposomal doxorubicin, in patients (pts) with advanced solid tumors: Dose escalation and expansion part of a multicenter open-label phase I trial (SAKK 65/16).	Hess D, Colombo I, Haefliger S, Rabaglio M, Bastian S, Schwitter M, Eckhardt K, Glaus Garzon J, Holer L, Hayoz S, Kopp C, Mc Laughlin A M, Kloft C, Sessa C, Stathis A, Halbherr S, Baumgartner C, Joerger M
	Oral presentation	DANTE	Surgical and pathological outcome in patients receiving perioperative atezolizumab in combination with FLOT chemotherapy vs. FLOT alone for resectable esophago-gastric adenocarcinoma: interim results from DANTE, a randomized, multicenter, phase IIb trial of the FLOT-AIO German Gastric Cancer Group and Swiss SAKK.	Al-Batran S, Lorenzen S, Thuss-Patience P C, Homann N, Schenk M, Lindig U, Heuer V, Kretschmar A, Goekurt E, Haag G M, Riera Knorrenschild J, Bolling C, Hofheinz R D, Angermeier S, Ettrich T J, Siebenhuener A R, Kopp C, Pauligk C, Götze T O, Gaiser T
	Poster	Lung ART EORTC	The Lung ART adjuvant radiotherapy phase 3 randomized trial: Impact of quality of resection in stage IIIA/IIIB patients. (Lung ART (IFCT-0503, UK NCRI, SAKK))	Thomas PA, Edwards JG, Rami-Porta R, Van Schil P, Mercier O, Le Rochais JP, Falcoz PE, Meunier JP, Gkika E, Kheira H, Riesterer O, Rosa Ghigna M, Bardet A, Le Pechoux C
	Poster discussion	SAKK 06/17	Perioperative chemo-immunotherapy with Durvalumab for operable muscle-invasive urothelial carcinoma (MIUC): primary analysis of the single arm phase II trial SAKK 06/17	Cathomas R, Rothschild S I, Hayoz S, Spahn M, Oezdemir B, Kiss B., Erdmann A, Aeppli S, Mach N, Strebel R T, Hadaschik B A, Berthold D R, Pless M, Zihler D, Schmid M, Schneider M, Musilova J, Petrusch U
ASH	Oral presentation	EBMT HCT vs CT	Increased LFS following hematopoietic cell transplantation as compared to conventional consolidation therapy in patients >60 years with AML in first complete remission and a matched donor: results of a randomized phase III study.	Niederwieser D, Hasenclever D, Berdel W, Biemond BJ, Al-Ali H, Chalandon Y, van Gelder M, Junghanß C, Gahrton G, Hänel M, Hehlmann R, Heinicke T, Hochhaus A, Iacobelli S, van Marwijk Kooy R, Kröger N, Janssen J, Jentzsch M, Breywisch F, Mohty M, Masouridi-Levrat S, Ossenkoppele G, Passweg J, Pönisch W, Schetelig J, Schliemann C, Schwind S, Stelljes M, Valk P, Löwenberg B, Cornelissen J
	Oral presentation	HOVON 132	Measurable Residual Disease Guided Therapy in Intermediate-Risk AML Patients Compared to an Unguided Cohort Using Propensity Score Matching	Tettero JM, Ngai LL, Bachas C, Breems DA, Fischer T, Gjertsen BT, Gradowska P, Griskevicius L, Janssen JJWM, Juliusson G, Maertens JA, Manz MG, Pabst T, Passweg J, Porkka K, Valk PJM, Lowenberg B, Ossenkoppele GJ, Cloos J

Conference	Abstract	Trial	Title	Authors
ASH	Poster	HOVON 132	Prospective Validation of CD34+CD38- Leukemic Stem Cell frequency in the HOVON-SAKK132 trial: Perspectives for Future Improvements	Ngai LL, Hanekamp D, Jansen F, Carbaat-Ham J, Hofland M, el-Fayet M, Kelder A, Oudshoorn-van Maarsbergen L, Scholten WJ, Snel AN, Bachas C, Tettero JM, Breems DA, Fischer T, Gjertsen BT, Griskevicius L, Juliusson G, Maertens J, Manz MG, Pabst T, Passweg J, Porkka K, Gradowska P, Löwenberg B, de Leeuw DC, Janssen JJWM, Ossenkoppele GJ, Cloos J
	Oral presentation	HD 21	Treatment Related Morbidity in Patients with Classical Hodgkin Lymphoma: Results of the Ongoing, Randomized Phase III HD21 Trial By the German Hodgkin Study Group	Borchmann P, Moccia A, Greil R, Hertzberg M, Schaub V, Hüttmann A, Keil F, Dierlamm J, Haesel M, Novak U, Meissner J, Zimmermann A, Mathas S, Zijlstra JM, Fosså A, Viardot A, Hertenstein B, Martin S, Giri P, Kamper P, Molin D, Kreissl S, Fuchs M, Schneider G, Rosenwald A, Klapper W, Eich H, Baues C, Hallek M, Dietlein M, Kobe C, Diehl V, Engert A
	Oral presentation	REMoDL-B	Five-year survival results from the Phase III randomised REMoDL-B trial (ISRCTN 51837425): molecular subtypes of diffuse large B-cell lymphoma show improved outcomes after bortezomib added to standard R-CHOP chemoimmunotherapy	Davies A, Stanton L, Caddy J, Barrans S, Wilding S, Saunders G, Mamot C, Novak U, McMillan A, Fields P, Pocock C, Collins GP, Stephens R, Cucco F, Sha C, Ahmed S, van Hoppe M, Tooze R, Care MA, Griffiths G, Du MQ, Westhead DR, Burton C, Schuh A, Johnson PWM
	Poster	REMoDL-B	Quality of Life Trajectories in Patients Treated with R-CHOP for Diffuse Large B-Cell Lymphoma As Part of the Remodl-B Trial (ISRCTN 51837425)	Hack J, Ralha I, Wilding S, Stanton L, Caddy J, Barrans S, Mamot C, Novak U, Burton C, McKay P, Campbel G, Davies Andrew, Johnson P
	Oral presentation	SAKK 38/07	External Validation Shows That Baseline PET Radiomics Outperform the IPI Risk Score for Prediction of Outcome in DLBCL	Eertink JJ, Zwezerijnen GJC, Heymans MW, Pieplenbosch S, Wiegers SE, Dührsen U, Hüttmann A, Kurch L, Hanoun C, Lugtenburg P, Barrington SF, Mikhaeel G, Ceriani L, Zucca E, Czibor S, Györke T, Chamuleau MED, Hoekstra OS, de Vet HCW, Boellaard R, Zijlstra JM
	Oral presentation	TRIANGLE	Efficacy and Safety of Ibrutinib Combined with Standard First-Line Treatment or As Substitute for Autologous Stem Cell Transplantation in Younger Patients with Mantle Cell Lymphoma: Results from the Randomized Triangle Trial By the European MCL Network	Dreyling M, Doorduijn JK, Gine E, Jerkeman M, Walewski J, Hutchings M, Mey U, Riise J, Trneny M, Vergote VKJ, Celli M, Shpilberg O, Gomes da Silva M, Leppa S, Jiang L, Pott C, Klapper W, Gözel D, Schmidt C, Unterhalt M, Ladetto M, Hoster E

Conference	Abstract	Trial	Title	Authors
<b>ASTRO</b>	Oral presentation	SAKK 09/10	Prognostic and Predictive Performance of a 24-Gene Post-Operative Radiation Therapy Outcomes Score (PORTOS) in a Phase 3 Randomized Trial of Dose-Intensified Salvage Radiotherapy after Radical Prostatectomy (SAKK 09/10)	Dal Pra A, Zwahlen D R, Liu V, Hayoz S, Spratt D E, Davicioni E, Proudfoot J A, Schär C, Hölscher T, Gut P, Polat B, Hildebrandt G, Mueller AC, Plasswilm L, Feng F Y, Pollack A, Thalmann G, Aebersold D, Ghadjar P
<b>CICON</b>	Poster	SAKK 11/16	Real-world comparator study: MVX-ONCO-1, a cell-based immunotherapy currently in Phase II, shows prolonged OS and PFS for patients with recurrent/metastatic Head & Neck squamous cell carcinoma (R/M HNSCC)	Mach N, Renaux J, Grogg J, Osterwalder B, Niklas N, Maisenhälder B, Ajmal A, Wolf AY, Shaid S, Borges M, Conceição L, Bento MJ, Vieira CM, Rordorf T, Brezina T, Jörger M, Fernandez E
<b>DGHO</b>	Oral presentation	SAKK 16/14	SAKK 16/14: Die Lokalisation von CD8-T-Zellen korreliert mit dem Überleben bei Patienten mit NSCLC im Stadium IIIA (N2) nach neoadjuvanter Immuntherapie	Sobottka B, Tochtermann F, Trueb M, Nowak M, Alborelli I, Leonards K, Manzo M, Keller E, Herzig P, Schmid D, Eboulet E, Hayoz S, Godar G, Schneider M, Koelzer VH, König D, Pless M, Jermann P, Zippelius A, Spasenija Savic Prince S, Rothschild SI, Koelzer VH
<b>DKK</b>	Poster	HD 16	PET-Guided Treatment in Patients with Early-Stage Favorable Hodgkin Lymphoma: Follow-up Analysis of the HD16 Trial by the German Hodgkin Study Group	Jacob AS, Fuchs M, Kaul H, Kobe C, Pabst T, Greil R, Eichenauer DA, Topp MS, Just M, Hertenstein B, Schaub V, Vogelhuber M, Zijlstra JM, Plütschow A, Baues C, Rosenwald A, Dietlein M, Borchmann P, Engert A
<b>EBCC</b>	Poster	SAKK 95/17	Effect of a 24 week home-based walking program on the incidence of aromatase inhibitor induced musculoskeletal pain: The WISE prospective, randomized, multicenter trial [SAKK 9517]	Honecker F, Müller A, Laurent R, Corke Mahbiz N, Schwitter M, Güth U, Jakob A, Schär S, Musilova J, Ribí K, Hoefnagels N
<b>EHA</b>	Oral presentation	HOVON 127/ SAKK 37/16	R-CODOX-M/R-IVAC versus dose-adjusted (DA)-EPOCH-R in patients with newly diagnosed high-risk Burkitt lymphoma; first results of a multi-center randomized HOVON/SAKK trial	Chamuleau M, Stenner F, Chitu D, Novak U, Minnema M, Visser O, Stevens W, Zenz T, van Imhoff G, Wu KL, Demandt A, Kersten MJ, Terpstra W, Tick L, Deeren D, van de Neste E, Gregor M, Veelken H, Bohmer L, Caspar C, Dirnhofer S, van de Brand M, de Jong D, Nijland M, Lugtenburg E



Conference	Abstract	Trial	Title	Authors
<b>ELCC</b>	Poster	ETOP BOOSTER	Impact of smoking status on the relative efficacy of the EGFR TKI/angiogenesis inhibitor combination therapy in advanced NSCLC A systematic review and meta analysis	Dafni U, Soo RA, Peters S, Tsourti Z, Vervita K, Han JY, De Castro J, Coate L, Früh M, Hashemi SMS, Nadal E, Carcereny E, Angeles Sala González M, Bernabé Caro R, Provencio Pulla M, Cuffe S, Ruepp B, Roschitzki-Voser H, Rosell R, Stahel RA
<b>ESHO</b>	Oral presentation	SAKK 09/10	Salvage-Radiation Therapy and regional Hyperthermia for biochemical recurrent prostate cancer after radical prostatectomy	Beck M, Müller AC, Zschaecck S, Hayoz S, Mehrhof F, Paulsen F, Schär S, Wegener D, Burock S, Ott O, Nadobny J, Oberacker E, Fietkau R, Zwahlen DR, Aebersold DM, Zips D, Ghadjar P
<b>ESMO</b>	Poster	SAKK 41/16	Neoadjuvant treatment with Regorafenib and Capecitabine combined with radio-therapy in locally advanced rectal cancer. A multicenter phase Ib trial (RECAP) SAKK 41/16	Bastian S, Joerger M, Baertschi D, Holzer L, Guckenberger M, Jochum W, Koeberle D, Siebenhüner AR, Wicki A, Berger MD, Winterhalder RC, Largiadèr CR, Löffler M, Mosna-Firlejczyk K, Fischer Maranta A, von Moos R
	Poster	SAKK 57/16	SAKK 57/16 Nab-Paclitaxel And Gemcitabine in soft tissue sarcoma (NAPAGE): Final results from the phase Ib/II trial with >2y median follow up	Digklia A, Kollár A, Kronig MN, Britschgi C, Rordorf T, Joerger M, F. Krasniqi F, Metaxas Y, Colombo I, Dietrich D, Chiquet S, Ribi K, Rothermundt C
	Oral presentation	STAMPEDE	Comparison of abiraterone acetate and prednisolone (AAP) or combination enzalutamide (ENZ) + AAP for metastatic hormone sensitive prostate cancer (mHSPC) starting androgen deprivation therapy (ADT): Overall survival (OS) results of 2 randomised phase III trials from the STAMPEDE protocol	Attard G, Murphy L R, Clarke N, Cross W, Gillessen S, Amos C L, Brawley C D, Jones R J, Pezaro C, Malik Z, Montazeri A H, Millman R, Cook A, Gilbert D C, Langley R E, Parker C C, Sydes M R, Brown L C, Parmar M K, James N D
	Oral presentation	SAKK 08/14	SAKK 08/14 - IMPROVE Investigation of metformin in patients with castration resistant prostate cancer in combination with enzalutamide vs. enzalutamide alone. A randomized, open label, phase II trial	Rothermundt C, Cathomas R, Gysel K, Fischer N, Pereira Mestre R, Hermanns T, Rothschild SI, Mach N, Mingrone W, Ciriolo M, Müller B, Erdmann A, Schär C, Mamot C, Bohanes P, Omlin A, Bastian S, Ribi K, Gillessen S
<b>ESMO IO</b>	Poster	SAKK 66/17	Thermal ablation followed by intratumoral injection of a novel immune stimulant IP-001 in patients with advanced solid tumors: Phase IB part of study SAKK 66/17	Joerger M, Knüsel P, Alexandre-Lafont E, Metaxas Y, Mark M, von Moos R, Gysel K, Eckhardt K, Glaus Garzon J, Koster KL, Wittwer Y, Tissot S, Flatz L, Alleruzzo L, Lam S, Anderson D, Chen W, Baskin-Bey E, Hode T

Conference	Abstract	Trial	Title	Authors
<b>ISHL12</b>	Oral presentation	HD 21	Treatment related morbidity in patients with classical Hodgkin Lymphoma: results of the ongoing, randomized phase III HD21 Trial by The German Hodgkin Study Group	Borchmann P, Moccia A, Greil R, Hertzberg M, Schaub V, Hüttmann A, Keil F, Dierlamm J, Hänel M, Novak U, Meissner J, Zimmermann A, Mathas S, Zijlstra JM, Fossa A, Viardot A, Hertenstein B, Martin S, Giri P, Kamper, P, Molin D, Kreissl S, Fuchs M, Schneider G, Rosenwald A, Klapper W, Eich H, Baues C, Hallek M, Dietlein M, Kobe C, Diehl V, Engert A
	Oral presentation	HD16 / HD17	Interim PET-guided treatment of early-stage nodular lymphocyte-predominant Hodgkin lymphoma: a subgroup analysis of the GHSG HD16 and HD17 studies	Eichenauer DA, Bühnen I, Fuchs M, Greil R, Moccia A, Zijlstra JM, Hartmann S, Kobe C, Dietlein M, Engert A, Borchmann P
<b>SABCS</b>	Oral presentation	IBCSG 48-14 POSITIVE	Pregnancy Outcome and Safety of Interrupting Therapy for women with endocrine responsive breast cancer: Primary Results from the POSITIVE Trial (IBCSG 48-14 / BIG 8-13)	Partridge AH, Niman SM, Ruggeri M, Peccatori FA, Azim HA Jr, Colleoni M, Saura C, Shimizu C, Sætersdal AB, Kroep JR, Mailliez A, Warner E, Borges VJ, Amant F, Gombos A, Kataoka A, Rousset-Jablonski C, Borstnar S, Takei J, Lee JE, Walshe JM, Ruíz Borrego M, Moore HCF, Saunders C, Bjelic-Radicic V, Susnjar S, Cardoso F, Smith KL, Ferreiro T, Ribi K, Ruddy KJ, El-Abed S, Piccart M, Korde LA, Goldhirsch A, Gelber RD, Pagani O
	Poster	SAKK 22/99	Safety analysis after 11 years of follow-up of the randomized phase III trial SAKK22/99: upfront chemotherapy in advanced HER2 positive breast cancer	Rabaglio M, Dietrich D, Scheibe B, Ruhstaller T, Nolè F, Eppenberger S, Oehlschlegel C, Hess D, Mamot C, Munzone E, Pestalozzi B, Aebi S, Vetter M, Thürlimann B, von Moos R, Zaman K, Pagani O
	Poster	SAKK 23/16	Axillary dissection to determine nodal burden to inform systemic therapy recommendations in patients with clinically node-positive breast cancer: Pre-planned substudy of TAXIS (OPBC-03, SAKK 23/16, IBCSG 57-18, ABCSG-53, GBG 101)	Weber WP, Matrai Z, Hayoz S, Tausch C, Henke D, Zwahlen DR, Gruber G, Zimmermann F, Ruhstaller T, Muenst S, Ackerknecht M, Kuemmel S, Bjelic-Radicic V, Smánykó V, Vrieling C, Satler R, Meyer I, Becciolini C, Bucher S, Simonson C, Fehr PM, Gabriel N, Maráz R, Sarlos D, Dedes KJ, Leo C, Berclaz G, Fansa H, Hager C, Reisenberger K, Sávolt A, Singer CF, Reitsamer R, Winkler J, Thanh Lam G, Fehr MK, Naydina T, Kohlik M, Clerc K, Ostapenko V, Fitzal F, Heidinger M, Maggi N, Schulz A, Markellou P, Lelièvre L, Egle D, Heil J, Knauer M, Mueller A, Kurzeder C

Conference	Abstract	Trial	Title	Authors
<b>SABCS</b>	Poster discussion	SAKK 23/16	Trends in neoadjuvant systemic therapy rates in Europe: Pre-planned substudy of TAXIS (OPBC-03, SAKK 23/16, IBCSG 57-18, ABCSG-53, GBG 101)	Weber WP, Matrai Z, Hayoz S, Henke D, Zwahlen DR, Gruber G, Zimmermann F, Ruhstaller T, Muenst S, Ackerknecht M, Kurzeder C, Kuemmel S, Bjelic-Radusic V, Smaykó V, Vrieling C, Satler R, Meyer I, Becciolini C, Bucher S, Simonson C, Fehr PM, Gabriel N, Maráz R, Sarlos D, Dedes KJ, Leo C, Berclaz G, Fansa H, Hager C, Reisenberger K, Sávolt A, Singer CF, Reitsamer R, Winkler J, Thanh Lam G, Fehr MK, Naydina T, Kohlik M, Clerc K, Ostapenko V, Fitzal F, Heidinger M, Maggi N, Schulz A, Markellou P, Lelièvre L, Egle D, Heil J, Knauer M, Mueller A, Tausch C
<b>SOHC</b>	Oral presentation	SAKK 16/14	SAKK 16/14: CD8 T cell positioning correlates with survival in stage IIIA(N2) NSCLC after neoadjuvant immunotherapy	Sobottka B, Tochtermann F, Trueb M, Nowak M, Alborelli I, Leonards K, Manzo M, Keller E, Herzig P, Schmid D, Hayoz S, Chiquet S, Schneider M, Koelzer VH, König D, Pless M, Jermann P, Zippelius A, Spasenija Savic Prince S, Rothschild SI
<b>WCLC</b>	Poster	SAKK 16/14	SAKK 16/14 – Peripheral immune cell populations in response to neoadjuvant durvalumab in patients with stage IIIA(N2) NSCLC	Schmid D, Trueb M, Herzig P, Gärtner-Pelham C, Alborelli I, Leonards K, Manzo M, Jermann P, Spasenija Savic Prince S, Keller E, Eboulet EI, Hayoz S, Godar G, Schneider M, Sobottka B, Nowak M, Tochtermann F, Koelzer VH, König D, Pless M, Zippelius A, Rothschild SI
	Oral presentation	SAKK 16/14	SAKK 16/14: CD8 T cell positioning correlates with survival in stage IIIA(N2) NSCLC after neoadjuvant immunotherapy	Sobottka B, Tochtermann F, Trueb M, Nowak M, Alborelli I, Leonards K, Manzo M, Keller E, Herzig P, Schmid D, Eboulet EI, Hayoz S, Godar G, Schneider M, Koelzer VH, König D, Pless M, Jermann P, Zippelius A, Spasenija Savic Prince S, Rothschild SI, Koelzer VH

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