SAKK

Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung
Groupe Suisse de Recherche Clinique sur le Cancer
Swiss Group for Clinical Cancer Research
Gruppo Svizzero di Ricerca Clinica sul Cancro

The Swiss Oncology Research Network

Jahresbericht

Der Jahresbericht 2010 ist auch als PDF-Datei auf unserer Webseite
www.sakk.ch publiziert.

Inhalt

Von Prof. Dr. Beat Thürlimann | Präsident SAKK

Unser Jahresbericht gibt Informationen über die Aktivitäten der SAKK im Verlauf des vergangenen Jahres. Die wissenschaftliche Aktivität ist nach aussen an den neu aktivierten Studien sowie den zahlreichen Präsentationen an internationalen Kongressen und den Publikationen in renommierten medizinischen Fachzeitschriften sichtbar.

Das Abschiedssymposium für den bisherigen SAKK Präsidenten, Prof. Richard Herrmann, war ein herausragendes Ereignis. Dabei wurde aus Sicht der Projektgruppen über die Ergebnisse der wichtigsten Studien während der Präsidentschaft von Prof. Herrmann berichtet. Beeindruckend war die Zahl der Publikationen aus allen Fachgebieten der Onkologie in den angesehensten Fachzeitschriften für klinische Krebsmedizin.

Wichtig für die weitere Entwicklung der SAKK sowie für die klinische Forschung in der Schweiz überhaupt ist die zunehmende Vernetzung im forschungspolitischen Umfeld. Diesem Aspekt werden Dr. Peter Brauchli, Geschäftsführer der SAKK, und ich weiterhin die notwendige Beachtung schenken. In den nächsten Jahren werden einige Herausforderungen auf die klinische Forschung in der Schweiz zukommen. Diese bieten jedoch auch wieder Möglichkeiten, Veränderungen im positiven Sinne mitzugestalten. In der zweiten Jahreshälfte gehörte insbesondere die Einflussnahme auf die Gesetzgebung für das neue Humanforschungsgesetz zu diesen Tätigkeiten. Dabei konnten wir zusammen mit den anderen Krebsorganisationen der Schweiz (Schweizerische Pädiatrische Onkologie Gruppe SPOG, Krebsforschung Schweiz KFS, Krebsliga Schweiz KLS und National Institute of Cancer Epidemiology and Research NICER) unsere Anliegen bei den Anhörungen in der nationalrätlichen Kommission einbringen.

Innerhalb der SAKK wird die Professionalisierung weiter vorangetrieben und das bereits begonnene Effizienzsteigerungsprogramm konsequent weitergeführt. Ziel ist es, die Abläufe innerhalb der SAKK zu optimieren, so dass die Projektaktivierungen schneller vorankommen. Eine neue IT-Lösung wird uns ebenfalls dabei helfen, dieses Ziel zu erreichen.

Wir sind also gut gerüstet, um das neue Jahr erfolgreich in Angriff nehmen zu können. Allen Beteiligten, welche zum Erfolg der SAKK intern und extern beigetragen haben, danke ich an dieser Stelle für ihre wertvolle Arbeit, insbesondere dem Direktor der SAKK, Dr. Peter Brauchli, und seinem Führungsteam.

Bedanken möchte ich mich auch bei all denjenigen, welche uns ideell, politisch und finanziell unterstützt haben, insbesondere dem Staatssekretariat für Bildung und Forschung SBF, der Stiftung Krebsforschung Schweiz, der Krebsliga Schweiz, der Schweizerischen Stiftung für Klinische Krebsforschung und der Industrie auf Basis von Projektkooperationen.

Von Dr. Peter Brauchli | Direktor SAKK

Wer wir sind

Die Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung (SAKK) hat sich im Sinne eines akademischen Forschungsinstituts mit nationalem Netzwerk der profitunabhängigen klinischen Krebsforschung verpflichtet. Die SAKK hat auch im vergangenen Jahr klinische Studien entwickelt, durchgeführt und ausgewertet. Darüber hinaus hat sie an verschiedenen politischen Prozessen teilgenommen und ihr Wissen und ihre Erfahrungen auch anderen Bereichen der klinischen Forschung zur Verfügung gestellt. Dank ihrer einmaligen Struktur ermöglicht die SAKK ihren 17 Mitgliedern, klinische Forschung auf höchstem Niveau durchzuführen. Insgesamt werden SAKK-Studien an über 50 Studienorten in der Schweiz und an ausländischen Spitälern durchgeführt. Dies ergibt ein grossartiges Netzwerk von motivierten Klinikern, Forschern und Mitarbeitenden. Das Abschiedssymposium zu Ehren des abgetretenen Präsidenten Prof. Dr. Richard Herrmann im Juni 2010 zeigte die Weiterentwicklung des Netzwerks über die letzten sechs Jahre sowie die Leistungs- und Motivationsfähigkeit ihrer Forscher eindrücklich auf.

Vorstand

Das Jahr 2010 war geprägt von mehreren Neubesetzungen im SAKK-Vorstand. Nach Ablauf der maximal zulässigen sechs Jahre im Amt als Präsident der SAKK trat Prof. Dr. Richard Herrmann zurück und wurde im Juli von Prof. Dr. Beat Thürlimann abgelöst. Weiter wurden Prof. Dr. Daniel Betticher, Prof. Dr. Martin Fey, Prof. Dr. Holger Moch und PD Dr. Arnaud Roth aus dem Vorstand verabschiedet. Neue Mitglieder sind Prof. Dr. Markus Borner, PD Dr. Viviane Hess, PD Dr. Miklos Pless und Prof. Dr. Achim Weber. An der jährlichen Retraite diskutierte der Vorstand die Ziele für die nächsten Jahre. Insbesondere wurden die strategischen Linien, welche ebenfalls im Antrag an das Staatssekretariat für Bildung und Forschung SBF für die neue Leistungsperiode 2013 bis 2016 formuliert sind, weiter ausgearbeitet.

Die SAKK setzt ihre Forschungsschwerpunkte weiterhin in den Bereichen

- Brustkrebs
- Gastro-intestinale Tumoren
- Leukämien
- Lungenkrebs
- Lymphome
- Urogenitale Tumoren
- New Anticancer Drugs

Die SAKK ist zudem bestrebt, die klinische Forschung auch auf Bereiche ausserhalb der priorisierten Projektgruppen, wie Kopf- und Halstumoren, Sarkome, Melanome, ZNS-Tumoren und gynäkologische Tumoren, auszudehnen.

In SAKK-Studien sollen zukünftig neben den Therapiekonzepten spezifische Fragestellungen in den Bereichen Prävention, Versorgungsforschung, Nachsorge, Behandlung von spezifischen Populationen (z.B. ältere Patienten) und Palliation berücksichtigt werden. Erklärtes Ziel ist es zudem, einer grösseren Anzahl Patienten die Möglichkeit der Teilnahme an klinischen Studien zu bieten und vermehrt auch eine führende Rolle bei der Durchführung von internationalen Studien einzunehmen.

Projektgruppen, Sektionen, Arbeitsgruppen

Die Aktivitäten im SAKK Netzwerk sind zahlreich und der Vorstand hatte viele neue Studienvorschläge zu beurteilen. Dieser innovative Geist ist wichtig für das Erreichen unserer Ziele und die weiterhin ansteigende Zahl von Projektvorschlägen ist sehr erfreulich. Einige Gruppen haben neue Präsidentinnen oder Präsidenten erhalten und an der Halbjahresversammlung im November wurde die neue Arbeitsgruppe Gynäkologische Tumoren gegründet. Dabei steht insbesondere die Zusammenarbeit zwischen Onkologen und Gynäkologen im Vordergrund, um vermehrt Forschung in diesem wichtigen Gebiet betreiben zu können.

Im Jahr 2010 ist zudem die neue Regelung über stimmberechtigte Mitglieder in den Projektgruppen eingeführt worden. Die Ausübung des Stimmrechts in einer Projektgruppe ist abhängig von der aktiven Teilnahme an den Studien und dem Einschluss evaluierbarer Patienten.

Studientätigkeit im Jahr 2010

Die SAKK hat letztes Jahr 832 Patienten in 44 klinische Studien eingeschlossen. Davon wurden 546 Patienten in selbstentwickelte Studien rekrutiert. Damit wurde erneut die Tätigkeit in SAKK-Studien ausgebaut. Der Anteil der ausländischen Studien, bei denen das SAKK-Koordinationszentrum das Protokoll nicht selber entwickelte, nahm hingegen wiederum leicht ab. Insgesamt wurden vom Vorstand neun klinische Studien in der finalen Prüfung akzeptiert. Sechs Vorschläge wurden bereits im Initial Assessment und eine Studie im Final Assessment abgelehnt. Drei weitere Studien scheiterten im Initial Assessment, weil Firmen keine Unterstützung anboten oder diese zurückzogen. Es freut uns, in diesem Zusammenhang zu erwähnen, dass das SBF bestätigte, dass wir alle an die SAKK gerichteten Anforderungen für die Projektevaluation bezüglich Entscheidungsverfahren und Gewaltenteilung erfüllen.

Die SAKK hat 2010 13 neue Studien entwickelt, sieben davon wurden bereits aktiviert. Es wurden 11 primäre Manuskripte zu wissenschaftlichen Studien veröffentlicht, an denen die SAKK entweder federführend oder massgeblich beteiligt war.

Insgesamt rekrutierten sieben SAKK-Studien auch im Ausland Patienten, nämlich in Deutschland, Frankreich, Italien, Belgien, Ungarn, Polen und Holland. Das Eröffnen von Zentren in der EU durch die SAKK läuft bei einigen Studien schnell und führt rasch zum Einschluss von Patienten. In anderen Projekten ist die Eröffnung von ausländischen Zentren wegen komplexer Logistik aber mit grossem Aufwand und einer zeitlichen Verzögerung verbunden.

Der Einschluss von Patienten war in den meisten Studien sehr erfreulich. Eine Herausforderung sind jedoch die langsam rekrutierenden Studien. Um frühzeitig Gegensteuer geben zu können, wird diese Problematik vermehrt überwacht und mit den Zentren Kontakt aufgenommen. Erfreulicherweise werden unsere Biobanken, die wir im Rahmen von klinischen Studien anlegen, verstärkt genutzt. Das gesammelte biologische Material wird untersucht und mit klinischen Daten verknüpft, sobald interessante Fragestellungen auftauchen. Dabei arbeiten wir auch mit biobanksuisse zusammen. Es ist zudem bemerkenswert, dass vermehrt klinische Fragestellungen ausgearbeitet werden, die keine Medikamente umfassen.

Weiterbildungsveranstaltungen

Die SAKK führte 2010 zwei Weiterbildungen für Prüfärzte und eine für Clinical Research Coordinators durch, um die klinische Forschungsarbeit zu professionalisieren. Bereits zum vierten Mal fand das Symposium State of the Art in Oncology Research statt, dieses Mal zum Thema «Personalized Medicine in Oncology». Die personalisierte Medizin ist ein viel diskutiertes Thema und die Referenten aus verschiedenen Fachgebieten zeigten auf, dass diese Art von Medizin zwar nicht neu ist, aber mit Biomarkern eine neue Dimension in der Behandlung und Forschung möglich wird. Alle Veranstaltungen stiessen auf reges Interesse und wurden von den verschiedenen Berufsgruppen gut besucht.

Kooperationen

Im sich rasch wandelnden Feld der klinischen Forschung in der Schweiz ist es für die SAKK unerlässlich, sich klar zu positionieren und ihre Interessen zu vertreten. Es wird daher vermehrt die Zusammenarbeit mit anderen Gruppen gesucht, um auch auf politischer Ebene unsere Anliegen wirksamer vorzubringen und die klinische Forschung einer breiteren Öffentlichkeit näherzubringen.

Die Zusammenarbeit mit der Swiss Clinical Trial Organisation (SCTO) konnte auf der operativen Ebene ausgebaut werden. Die SAKK ist gerne bereit, ihre Erfahrung weiterzugeben und von produktiven Prozessen in der SCTO zu profitieren. Dabei zeigte sich, dass die beiden Organisationen zwar unterschiedlich funktionieren und unterschiedliche Ziele haben, aber das gemeinsame Interesse teilen, die klinische Forschung am Standort Schweiz zu stärken.

Jahresrechnung

Die Jahresrechnung 2010 schliesst mit einem Defizit. Diese Situation war bereits Mitte Jahr absehbar. Das Defizit ist massgeblich durch fehlende Einnahmen wegen Verzögerungen in der Studienaktivierung und durch langsameren Einschluss von Patienten verursacht. Eine Analyse führte bereits zu korrektiven Massnahmen, wie beispielsweise

eine verbesserte Projektunterstützung und die Erhöhung der Verbindlichkeit bei der Einhaltung von Zeitplänen für Mitarbeitende und Personen aus dem Netzwerk. Auch wird der Vorstand künftig vermehrt die zeitgerechte Durchführbarkeit beim Aktivierungsentscheid einer Studie bewerten. Er fasste zudem den strategischen Entscheid, in die Beschaffung von Drittmitteln zu investieren.

Besonders ins Gewicht fällt die Übernahme von Kosten, die auch im Rahmen der Standardbehandlung entstehen würden. Aufgrund der momentanen Interpretation der gesetzlichen Bestimmungen ist der Sponsor einer klinischen Studie teilweise gezwungen, auch die Kosten für Standardmassnahmen und -therapien von Patienten, die im Rahmen von klinischen Studien behandelt werden, zu übernehmen.

Electronic Data Capture EDC
2010 sind insgesamt fünf Studien in der selbstentwickelten EDC-Lösung SINATRAS implementiert und den Zentren zugänglich gemacht worden. Allerdings mussten wir im Laufe des Jahres feststellen, dass diese Lösung den heutigen Ansprüchen nur mehr mit grossen Investitionen genügen kann. Nach einer intensiven Evaluation wurde beschlossen, das kommerzielle EDC-System secuTrial® – das auch von den Clinical Trial Units in Zukunft benutzt wird – als neue EDC-Softwarelösung zu etablieren.

Nationales Krebsprogramm
Die Ausgestaltung des neuen Nationalen Krebsprogramms (NKP) 2011–2015 ist weit fortgeschritten und das Programm wird 2011 publiziert. Das NKP ist ein gesamtschweizerisches, koordinierendes politisches Instrument mit dem Ziel, die Erforschung, Verhütung, Früherkennung und Behandlung von Krebs sowie die Bewältigung von Krankheitsfolgen zu verbessern. Die SAKK hat die beiden Kapitel Forschung und Therapie erarbeitet und wird die Hauptverantwortung für die Umsetzung im Bereich Forschung übernehmen. Das NKP ist ein wichtiges Instrument, um vermehrt Prozesse auf politischer Ebene weiterzubringen und die politische Sichtbarkeit der SAKK zu erhöhen. Dieses Projekt ist eines der Hauptanliegen der nächsten Jahre für das Schweizerische Krebsbekämpfungsnetzwerk. Im Rahmen des NKP ergibt sich eine geschätzte und fruchtbare Zusammenarbeit zwischen den verschiedenen Organisationen im Haus der Krebsliga.

Politische Arbeit
Die SAKK engagiert sich gemeinsam mit der Krebsliga Schweiz und Oncosuisse im Rahmen des politischen Prozesses zur Ausarbeitung des Humanforschungsgesetzes. Die SAKK hat weitere Prozesse zu Vereinfachungen in der Durchführung klinischer Forschung angestossen und auch die Problematik der Kostenübernahme von Pflege und Behandlung im Rahmen von klinischen Studien aufgebracht. Hier zeigt sich deutlich, dass die SAKK eine akademische Organisation mit langjähriger praktischer Erfahrung in der Studiendurchführung ist und von den gesundheitspolitischen Instituitonen im Land als Ansprechpartner geschätzt wird.

Es fanden sehr wichtige und produktive Treffen mit der Arbeitsgemeinschaft der Ethikkommissionen AGEK, Swissmedic, dem Bundesamt für Gesundheit BAG, dem Staatssekretariat für Bildung und Forschung SBF, dem Schweizerischen Nationalfonds SNF und der Swiss Clinical Trial Organisation SCTO statt.

Koordinationszentrum
Am SAKK-Koordinationszentrum haben wir 2010 eine Konsolidierungsphase eingeleitet. Um die wachsende Menge an zu entwickelnden Studien und die damit zusammenhängende Arbeit zu bewältigen, wurde die Anzahl der von der SAKK fest angestellten Mitarbeitenden auf Ende 2010 um zwei Personen auf 52 erhöht (4360 Stellenprozente). Für die IT-Abteilung konnte Cornelia Kruschel als neue Leiterin gewonnen werden. Sie hat ihre Arbeit im April 2010 aufgenommen. Neu geschaffen wurde die Position eines Medical Advisors. Dieser unterstützt die Studienleiter bei der Entwicklung der Studienpläne und überwacht zusammen mit den nichtärztlichen Mitarbeitenden am Koordinationszentrum und dem Präsidenten die Sicherheit der Patienten. Dr. Arnoud Templeton arbeitet als Medizinischer Onkologe am Kantonsspital St. Gallen und mit einem Pensum von 50 % am Koordinationszentrum.

Der Einsatz aller Mitarbeitenden des Koordinationszentrums war grossartig. Für den unermüdlichen Einsatz für die Ziele der SAKK bedanke ich mich ganz herzlich bei den Abteilungsleitenden und ihren Teams.

Präsident
Prof. Dr. Beat Thürlimann
Kantonsspital St. Gallen

Vize-Präsident
Dr. Roger von Moos
Kantonsspital Chur

Prof. Stephan Bodis
Kantonsspital Aarau

Prof. Dr. Markus Borner
Spitalzentrum Biel
Inselspital Bern

PD Dr. Yves Chalandon
Hôpital Universitaire
de Genève

Prof. Michele Ghielmini
Ospedale Regionale
Lugano

PD Dr. Viviane Hess
Universitätsspital Basel

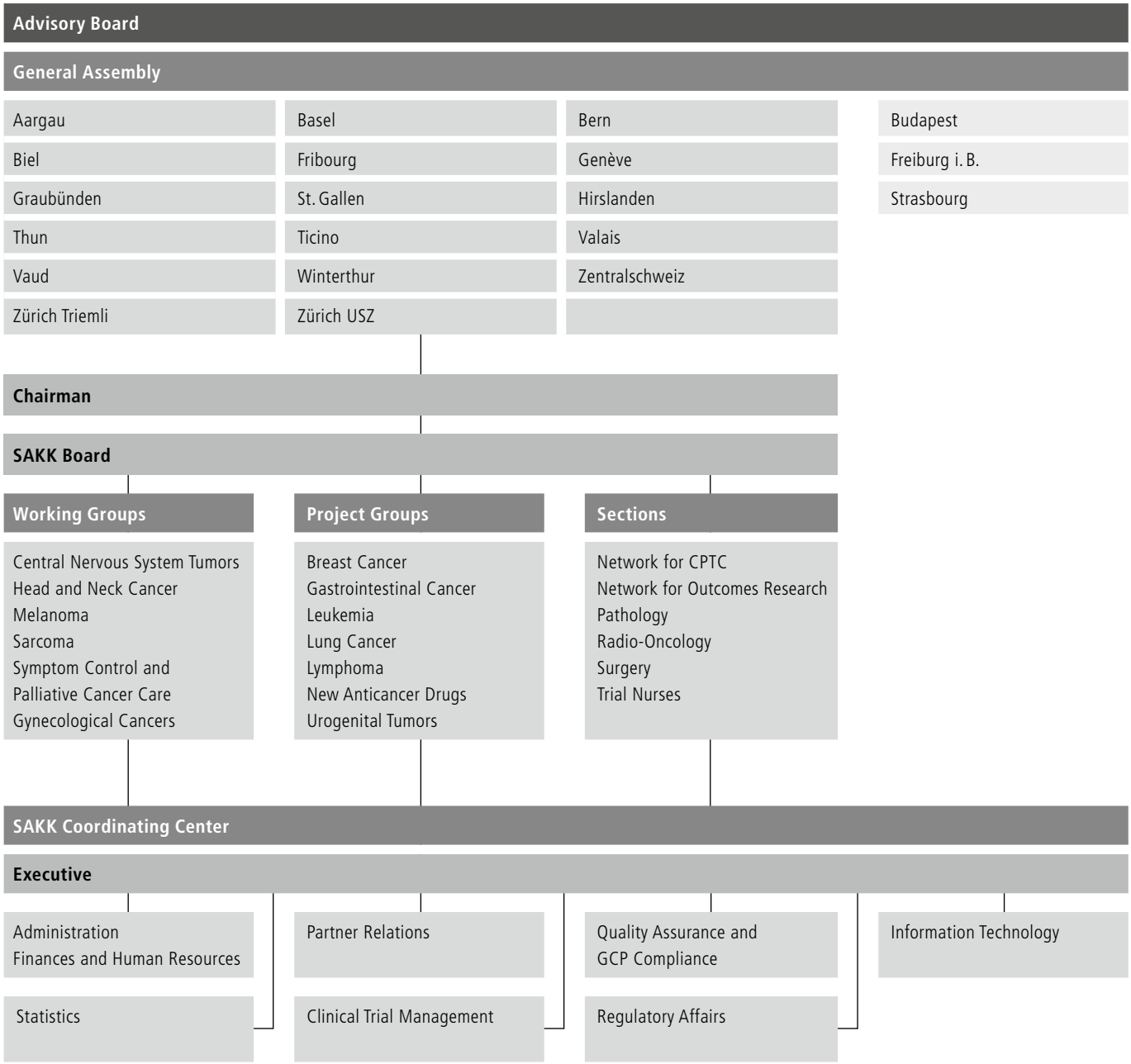
Prof. Walter Richard Marti
Kantonsspital Aarau

PD Dr. Miklos Pless
Kantonsspital Winterthur

Prof. Christoph Renner
Universitätsspital Zürich

Prof. Dr. Achim Weber
Universitätsspital Zürich

Organigram Swiss Group for Clinical Cancer Research (SAKK)



SAKK Führungskräfte, Ehrungen, Beförderungen, Ernennungen

Chefärzte
- Prof. Dr. Stefan Aebi, Chefarzt Medizinische Onkologie, Kantonsspital Luzern
- Prof. Dr. Jakob Passweg, Chefarzt Hämatologie, Universitätsspital Basel

Leitende Ärzte
- Prof. Dr. Christoph Driessen, Leitender Arzt, Kantonsspital St. Gallen
- Prof. Dr. Jens Huober, Leitender Arzt, Brustzentrum Kantonsspital St. Gallen
- PD Dr. Florian Strasser, Leitender Arzt, Kantonsspital St. Gallen

Oberärzte
- Dr. Federica Chiesa, Oberärztin, Brustzentrum Kantonsspital St. Gallen
- Dr. Markus Jörger, Oberarzt, Brustzentrum Kantonsspital St. Gallen
- Dr. Salomé Riniker, Oberärztin, Brustzentrum Kantonsspital St. Gallen

Ernennungen
- Prof. Dr. Jane Apperley, Chair of the Department of Haematology, Department of Medicine, Imperial College London: Mitglied Wissenschaftlicher Beirat SAKK
- Prof. Dr. Markus Borner, Chefarzt Medizinische Onkologie, Spitalzentrum Biel und Leitender Arzt Medizinsche Onkologie, Inselspital Bern: Mitglied SAKK Vorstand
- PD Dr. Mathias Fehr, Chefarzt Frauenklinik, Kantonsspital Frauenfeld: Co-Präsident SAKK Arbeitsgruppe Gynäkologische Tumore
- PD Dr. Viviane Hess, Oberärztin Onkologie, Universitätsspital Basel: Mitglied SAKK Board
- Dr. Andreas Hottinger, Hôpital Cantonal Universitaire Genève: Präsident SAKK Arbeitsgruppe ZNS-Tumore
- Dr. Michael Montemurro, Centre Pluridisciplinaire d'Oncologie, CHUV Lausanne: Präsident Projektgruppe Gastro-intestinale Tumore
- Prof. Dr. Jakob Passweg, Chefarzt Hämatologie, Universitätsspital Basel: Präsident Krebsliga Schweiz
- PD Dr. Miklos Pless, Chefarzt Medizinische Onkologie, Kantonsspital Winterthur: Mitglied SAKK Vorstand
- Prof. Dr. Cristiana Sessa, Ospedale San Giovanni Bellinzona: Co-Präsidentin SAKK Arbeitsgruppe Gynäkologische Tumore
- Prof. Dr. Simon Thompson, Director MRC Biostatistics Unit Institute of Public Health, Cambridge: Mitglied Wissenschaftlicher Beirat SAKK
- Dr. Roger von Moos, Leitender Arzt, Kantonsspital Chur: SAKK Vize-Präsident
- Prof. Dr. Achim Weber, Leitender Arzt Institut für Klinische Pathologie, Universitätsspital Zürich: Mitglied SAKK Vorstand und Präsident SAKK Sektion Pathologie
- Prof. Dr. Franz Zimmermann, Institut für Radio-Onkologie, Universitätsspital Zürich: Präsident SAKK Arbeitsgruppe Kopf- und Halstumore

Preisverleihungen
- Prof. Dr. Jacques Bernier, Service de Radio-Oncologie Genolier Medical Network, Clinique de Genolier: Claudius Regaud Medaille
- Dr. Michael Montemurro, Centre Pluridisciplinaire d'Oncologie, CHUV Lausanne: GIST Preis
- Prof. Dr. John O. Prior, Centre Pluridisciplinaire d'Oncologie, CHUV Lausanne: GIST Preis

Halbjahresversammlung Juni

Am 17. Juni 2010 fand die Sommer-Halbjahresversammlung der SAKK in Bern statt, an der über 250 Onkologiespezialisten, Vertreter von Pharmaunternehmen und Mitarbeitende des SAKK-Koordinationszentrums teilnahmen.

Im Rahmen der SAKK-Mitgliederversammlung genehmigten die Teilnehmer die Jahresrechnung der SAKK und erteilten den Vorstandsmitgliedern die Décharge. Zudem wählte die Versammlung zwei neue Vorstandsmitglieder als Ersatz für Prof. Dr. Beat Thürlimann vom Kantonsspital St. Gallen, der neu die SAKK präsidiert, sowie für Prof. Dr. Martin Fey vom Inselspital Bern. Neu im Vorstand der SAKK sind PD Dr. Viviane Hess vom Universitätsspital Basel sowie Prof. Dr. Markus Borner vom Spitalzentrum Biel und dem Inselspital Bern.

Die SAKK organisierte an der Halbjahresversammlung im Juni ein Abschiedssymposium für Prof. Dr. Richard Herrmann. Prof. Herrmann trat auf Ende Juni als SAKK-Präsident zurück, nachdem er die maximale Amtszeit von sechs Jahren erfüllt hatte. Prof. Dr. Beat Thürlimann trat als sein Nachfolger am 1. Juli 2010 das Amt als neuer SAKK-Präsident an.

Prof. Dr. Markus Borner

PD Dr. Viviane Hess

Dr. Michael Montemurro und Prof. Dr. John Prior mit Helga Meier und Prof. Dr. Urs Metzger vom Preiskomitee.

Halbjahresversammlung November
Die SAKK hielt ihre Winter-Halbjahresversammlung am 25. und 26. November 2010 in Basel ab. Ergänzend zu den Sessionen der verschiedenen SAKK-Forschungsgruppen fanden das SAKK-Symposium sowie das von den Firmen Boehringer Ingelheim und Roche Pharma (Schweiz) gesponserte Satellitensymposium statt.

Als Auftakt zum SAKK-Symposium verlieh die GIST-Gruppe Schweiz den beiden Krebsforschern Dr. Michael Montemurro sowie Prof. Dr. John Prior vom CHUV Lausanne den GIST-Preis 2010.

Dieser ist mit CHF 10 000 dotiert und zeichnet jährlich wissenschaftliche Arbeiten aus, die zur Verbesserung der Therapie von Gastrointestinalen Stromatumoren (GIST) beitragen. Während des anschliessenden SAKK-Symposiums stellte Oncosuisse-Präsident Prof. Dr. Richard Herrmann das Nationale Krebsprogramm (NKP) der Schweiz 2011–2015 vor.

An der SAKK-Mitgliederversammlung wurden zwei neue Vorstandsmitglieder gewählt sowie vier Vorstandsmitglieder wiedergewählt. Die neu gewählten Vorstandsmitglieder sind PD Dr. Miklos Pless vom Kantonsspital Winterthur sowie Prof. Dr. Achim Weber vom Universitätsspital Zürich. Prof. Weber wurde von der SAKK Sektion Pathologie zum Präsidenten gewählt und vertritt im SAKK-Vorstand die Pathologie.

Zudem wählte die Versammlung einstimmig zwei neue Mitglieder des wissenschaftlichen Beirats: Die Hämatologin Jane Apperley vom Imperial College in London, UK, und den Statistiker Simon Thompson von der MRC Biostatistics Unit in Cambridge, UK. Sie ersetzen Andreas Neubauer vom Universitätsklinikum Marburg, Deutschland, sowie Mahesh Parmar, Medical Research Council, London, UK.

Schliesslich wurde an der Winter-Halbjahresversammlung eine neue Arbeitsgruppe für Gynäkologische Tumoren gegründet.

Prof. Dr. Achim Weber

PD Dr. Miklos Pless

Prof. Dr. Richard Herrmann

Danksagung an Prof. Dr. Richard Herrmann

Prof. Dr. Richard Herrmann hat im Juni 2004 die Präsidentschaft der SAKK übernommen, zu einem Zeitpunkt, als sich die klinische Krebsforschung in der Schweiz in der Krise befand. Auslöser war die Einführung des neuen Heilmittelgesetzes, dessen Anforderungen die SAKK ins Schleudern brachten. Die SAKK lag Richard Herrmann am Herzen und er war sich bewusst, dass ihre Tätigkeit für die Gesellschaft zu wichtig war, als dass man sie hätte auflösen dürfen. Er wusste um das Potenzial der klinischen Krebsforschung und nahm sich vor, Energie und Zeit zu investieren, um die SAKK wieder auf den Pfad des Erfolgs zu führen.

Richard Herrmann hat die SAKK dort hingeführt, wo sie heute steht. Die SAKK ist eine starke Organisation mit einem eigenen Koordinationszentrum. Richard Herrmann hat den Ausbau des Koordinationszentrums unterstützt und damit dessen Produktivität massgeblich erhöht. Heute wird es als Kompetenzzentrum wahrgenommen. Die SAKK hat in der klinischen Forschung ihren festen Platz wiedergefunden und gilt als Referenzorganisation. Unter dem Dach der SAKK führen Kliniker verschiedener Disziplinen wieder vermehrt gemeinsame multimodale Forschungsprojekte durch. Heute wollen Spitäler nicht nur Studien durchführen, weil sie dazu verpflichtet sind, sondern weil klinische Forschung ein allgemein anerkanntes Qualitätsmerkmal für eine Klinik ist und der Institution und den Forschenden zu internationaler Anerkennung verhilft. Die professionelle klinsche Forschung wird vermehrt auch als Qualitätsicherungsmassnahme anerkannt und dient so direkt den Patienten.

Richard Herrmann hat die Organisation während den sechs Jahren als SAKK-Präsident mit Umsicht und Weitblick geführt. Auch als Person ist er ein Vorbild. Er hat gezeigt, was es bedeutet, Verantwortung zu übernehmen und mit Beharrlichkeit Ziele zu verfolgen. Wir danken Richard Herrmann für alles, was er für die SAKK getan hat; für deren Leitung, für die Mitarbeitenden des SAKK-Koordinationszentrums, für die Forschenden und für die Patienten.

By Ursula Kühnel, Head Clinical Trial Management

Summary of Activities

In 2010, a total of 832 patients were included in 44 clinical trials coordinated by SAKK:

	2010	2009
Total patients from Switzerland	787	790
Total patients from foreign countries	45	41
Total	**832**	**831**

	2010		2009	
	Patients	Trials	Patients	Trials
Total patients in SAKK trials	546	27	481	20
Total patients in trials of cooperative groups (without IBCSG)	102	7	132	11
Total patients in IBCSG trials	160	7	173	7
Total patients in Sendo trials	24	3	45	3
Total	**832**	**44**	**831**	**41**

Trials open for accrual in 2010

Urogenital Cancers

SAKK 08/08 | Everolimus first-line therapy in non-rapidly progressive castration resistant prostate cancer (CRPC). A multicenter phase II trial

SAKK 08/09 | Metformin in castration resistant prostate cancer. A multicenter phase II trial

STAMPEDE | Systemic therapy in advancing or metastatic prostate cancer: Evaluation of drug efficacy. A 5-stage multi-arm randomised controlled trial

Lung Cancer

SAKK 15/08 | Carboplatin and paclitaxel with ASA404 as first line chemotherapy for extensive-stage small-cell lung cancer

SAKK 16/00 | Preoperative radiochemotherapy vs. chemotherapy alone in non-small cell lung cancer (NSCLC) patients with mediastinal lymph node metastases (stage IIIA, N2)

SAKK 16/08 | Preoperative chemotherapy and radiotherapy with concomitant cetuximab in non-small cell lung cancer (NSCLC) patients with IIIB disease. A multicenter phase II trial

SAKK 17/04 | Neoadjuvant chemotherapy and extrapleural pneumonectomy of malignant pleural mesothelioma (MPM) with or without hemithoracic radiotherapy

SAKK 19/09 | Bevacizumab, pemetrexed and cisplatin, or erlotinib and bevacizumab for advanced non-squamous NSCLC stratified by EGFR mutation status. A multicenter phase II trial including biopsy at progression (BIO-PRO trial)

Breast Cancers

SAKK 21/08 | Fulvestrant with or without AZD6244, a mitogen-activated protein kinase kinase (MEK) 1/2 inhibitor, in advanced stage breast cancer progressing after aromatase inhibitor: a randomized placebo-controlled double-blind phase II trial

SAKK 22/99 | Randomized phase III trial of Herceptin® followed by chemotherapy plus Herceptin® versus the combination of Herceptin® and chemotherapy as palliative treatment in patients with HER2-overexpressing advanced/metastatic breast cancer

SAKK 24/09 | Safety and tolerability of bevacizumab plus paclitaxel vs. bevacizumab plus metronomic cyclophosphamide and capecitabine as first-line therapy in patients with HER2-negative metastatic or locally recurrent breast cancer. A multicenter, randomized phase III trial

SAKK 92/08 | Local antiperspirant for prevention of palmar-plantar erythrodysesthesia (PPE) in patients treated with pegylated liposomal doxorubicin: A randomized, multicenter, double blinded, phase III trial

IBCSG 22-00 | Low-dose cytotoxics as «anti-angiogenesis treatment» following adjuvant induction chemotherapy for patients with ER-negative and PgR-negative breast cancer

IBCSG 23-01 | A randomized trial of axillary dissection vs. no axillary dissection for patients with clinically node negative breast cancer and micro-metastases in the sentinel node

IBCSG 24-02 | BIG 2-02/ SOFT suppression of ovarian function trial (SOFT). A phase III trial evaluating the role of ovarian function suppression and the role of exemestane as adjuvant therapies for premenopausal women with endocrine responsive breast cancer

IBCSG 25-02 | A phase III trial evaluating the role of exemestane plus GnRH analogue as adjuvant therapy for premenopausal women with endocrine responsive breast cancer

IBCSG 27-02 | BIG 1-02/NSABP Trial B-37. A randomized clinical trial of adjuvant chemotherapy for radically resected loco-regional relapse of breast cancer

IBCSG 35-07 | BIG 1–07 SOLE study of letrozole extension. A phase III trial evaluating the role of continuous letrozole versus intermittent letrozole following 4 to 6 years of prior adjuvant endocrine therapy for postmenopausal women with hormone-receptor positive, node positive early stage breast cancer

IBCSG 36-07 | ALTTO (adjuvant lapatinib and/or trastuzumab treatment optimisation) study. A randomised, multicentre, open-label, phase III study of adjuvant, lapatinib, trastuzumab their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer

IBIS-II | Prevention: anastrozole vs placebo in postmenopausal women at increased risk of breast cancer
treatment: tamoxifen vs. anastrazole in postmenopausal women with DCIS

Leukemias

SAKK 30/07 | 5-Azacytidine to treat acute myeloid leukemia in elderly or frail patients not suitable for intensive chemotherapy. A multicenter phase II trial

APL 2006 | Randomized phase III trial assessing the role of arsenic trioxide and/or ATRA during consolidation course in newly diagnosed acute promyelocytic leukemia (APL)

CLL 7 | Randomized phase III trial comparing early treatment with fludarabine, cyclophosphamide + rituximab versus deferred treatment in untreated Binet stage A patients with high risk of progression

CLL 10 | Phase III trial of combined immunochemotherapy with fludarabine, cyclophosphamide and rituximab (FCR) versus bendamustine and rituximab (BR) in patients with previously untreated chronic lymphocytic leukaemia

CML IV | Randomisierter kontrollierter Vergleich von Imatinib, Imatinib und Interferon, Imatinib und niedrig dosiertes AraC, Interferon-Standardtherapie

GRAALL 2005 | Protocole multicentrique de traitement des leucémies aiguës lymphoblastiques (LAL) de l'adulte jeune (18–59 ans)

HOVON 92 | Randomized study to assess the added value of laromustine in combination with standard remission-induction chemotherapy in patients aged 18–65 yrs with previously untreated acute myeloid leukemia (AML) or myelodysplasia (MDS) (RAEB with IPSS > = 1.5). A multicenter phase III trial

HOVON 102 | Randomized study with a run-in feasibility phase to assess the added value of Clofarabine in combination with standard remission-induction chemotherapy in patients aged 18–65 yrs with previously untreated acute myeloid leukemia (AML) or myelodysplasia (MDS) (RAEB with IPPS > 1.5)

Lymphomas

SAKK 36/06 | Everolimus (RAD001) for the treatment of patients with relapsed or therapy resistant mantle cell lymphoma

SAKK 37/05 | Ibritumomab tiuxetan and high-dose melphalan as conditioning regimen before autologous stem cell transplantation for elderly patients with lymphoma in relapse or resistant to chemotherapy. A multicenter phase I trial

SAKK 38/07 | Prospective evaluation of the predictive value of PET in patients with diffuse large B-cell-lymphoma under R-CHOP-14. A multicenter study

SAKK 38/08 | Rituximab, bendamustine and lenalidomide in patients with relapsed or refractory aggressive B-cell lymphoma not eligible for high dose chemotherapy. A phase I/II trial

EBMT MMVAR | A randomized controlled study of Velcade (bortezomib) plus thalidomide plus dexamethasone compared to thalidomide plus dexamethasone for the treatment of myeloma patients progressing or relapsing after autologous transplantation

HD 16 | HD16 for early stages: treatment optimization trial in the first-line treatment of early stage Hodgkin lymphoma; treatment stratification by means of FDG-PET

HD 18 | Therapieoptimierungsstudie in der Primärtherapie des fortgeschrittenen Hodgkin Lymphoms: Therapiestratifizierung mittels FDG-PET

Gastrointestinal Cancers

SAKK 40/04 | Clinical function after total mesorectal excision and rectal replacement. A prospective randomized trial comparing side-to-end anastomosis, colon-J-pouch and straight coloanal anastomosis

SAKK 41/06 | Bevacizumab maintenance versus no maintenance after stop of first-line chemotherapy in patients with metastatic colorectal cancer. A randomized multicenter phase III non-inferiority trial

SAKK 41/07 | Neoadjuvant radiotherapy and capecitabine with or without panitumumab in patients with advanced, K-ras unmutated rectal cancer. A randomized multicenter phase II trial

SAKK 41/08 | Neoadjuvant radiotherapy combined with capecitabine and sorafenib in patients with advanced, K-ras mutated rectal cancer. A multicenter phase I/IIa trial

SAKK 56/07 | Dasatinib first-line treatment in gastrointestinal stromal tumors. A multicenter phase II trial

SAKK 75/08 | Multimodal therapy with and without cetuximab in patients with locally advanced esophageal carcinoma. An open-label phase III trial

SAKK 77/07 | External beam radiotherapy for unresectable hepatocellular carcinoma. A multicenter phase I/II trial

SAKK 77/08 | Sorafenib alone or in combination with everolimus in patients with unresectable hepatocellular carcinoma. A randomized multicenter phase II trial

SAKK 77/09 | A phase I open label/phase II randomized, double-blind, multicenter trial investigating the combination of everolimus and TransArterial ChemoEmbolisation (TACE) with doxorubicin in patients with hepatocellular carcinoma eligible for TACE

Supportive Care

SAKK 95/06 | A multicenter randomized controlled phase III study of longitudinal electronic monitoring of symptoms and syndromes associated with advanced cancer in patients receiving anticancer treatment in palliative intention

New Drugs

SAKK 65/08 | Phase I trial of nelfinavir and bortezomib in advanced hematologic malignancies

Further projects 2010

SAKK 29/10 | Comprehensive screening of a panel of breast cancer susceptibility genes in BRCA1/BRCA2-mutation negative families

SAKK 89/09 | End-of-life delivery of care patterns in Swiss cancer patients

Trials activated in 2010

Urogenital Cancers

SAKK 08/09 | Metformin in castration resistant prostate cancer. A multicenter phase II trial

STAMPEDE | Systemic therapy in advancing or metastatic prostate cancer: evaluation of drug efficacy. A 5-stage multi-arm randomised controlled trial

Lung Cancer

SAKK 15/08 | Carboplatin and paclitaxel with ASA404 as first line chemotherapy for extensive-stage small-cell lung cancer

SAKK 16/08 | Preoperative chemotherapy and radiotherapy with concomitant cetuximab in non-small cell lung cancer (NSCLC) patients with IIIB disease. A multicenter phase II trial

SAKK 19/09 | Bevacizumab, pemetrexed and cisplatin, or erlotinib and bevacizumab for advanced non-squamous NSCLC stratified by EGFR mutation status. A multicenter phase II trial including biopsy at progression (BIO-PRO trial)

Breast Cancers

SAKK 21/08 | Fulvestrant with or without AZD6244, a mitogen-activated protein kinase kinase (MEK) 1/2 inhibitor, in advanced stage breast cancer progressing after aromatase inhibitor: a randomized placebo-controlled double-blind phase II trial

SAKK 24/09 | Safety and tolerability of bevacizumab plus paclitaxel vs. bevacizumab plus metronomic cyclophosphamide and capecitabine as first-line therapy in patients with HER2-negative metastatic or locally recurrent breast cancer. A multicenter, randomized phase III trial

IBCSG 27-02 | BIG 1-02/NSABP Trial B-37: a randomized clinical trial of adjuvant chemotherapy for radically resected loco-regional relapse of breast cancer

Leukemias

HOVON 102 | Randomized study with a run-in feasibility phase to assess the added value of clofarabine in combination with standard remission-induction chemotherapy in patients aged 18–65 yrs with previously untreated acute myeloid leukemia (AML) or myelodysplasia (MDS) (RAEB with IPPS > 1.5)

Lymphomas

HD 16 | HD16 for early stages: Treatment optimization trial in the first-line treatment of early stage Hodgkin lymphoma; treatment stratification by means of FDG-PET

Gastrointestinal Cancers

SAKK 75/08 | Multimodal therapy with and without cetuximab in patients with locally advanced esophageal carcinoma. An open-label phase III trial

SAKK 77/09 | A phase I open label/phase II randomized, double-blind, multicenter trial investigating the combination of everolimus and TransArterial ChemoEmbolisation (TACE) with doxorubicin in patients with hepatocellular carcinoma eligible for TACE

New Drugs

SAKK 65/08 | Phase I trial of nelfinavir and bortezomib in advanced hematologic malignancies

Trials closed in 2010

Urogenital Cancers

SAKK 08/08 | Everolimus first-line therapy in non-rapidly progressive castration resistant prostate cancer (CRPC). A multicenter phase II trial

Leukemias

SAKK 30/07 | 5-Azacytidine to treat acute myeloid leukemia in elderly or frail patients not suitable for intensive chemotherapy. A multicenter phase II trial

CLL 7 | Randomized phase III trial comparing early treatment with fludarabine, cyclophosphamide + rituximab versus deferred treatment in untreated Binet stage A patients with high risk of progression

HOVON 92 | Randomized study to assess the added value of laromustine in combination with standard remission-induction chemotherapy in patients aged 18–65 yrs with previously untreated acute myeloid leukemia (AML) or myelodysplasia (MDS) (RAEB with IPSS > = 1.5). A multicenter phase III trial

Lymphomas

SAKK 36/06 | Everolimus (RAD001) for the treatment of patients with relapsed or therapy resistant mantle cell lymphoma

SAKK 38/07 | Prospective evaluation of the predictive value of PET in patients with diffuse large B-cell-lymphoma under R-CHOP-14. A multicenter study

EBMT MMVAR | A randomized controlled study of Velcade (bortezomib) plus thalidomide plus dexamethasone compared to thalidomide plus dexamethasone for the treatment of myeloma patients progressing or relapsing after autologous transplantation

Gastrointestinal Cancers

SAKK 41/07 | Neoadjuvant radiotherapy and capecitabine with or without panitumumab in patients with advanced, K-ras unmutated rectal cancer. A randomized multicenter phase II trial

New Drugs

SKSD00701 | Dose-finding study of satraplatin in combination with oral vinorelbine in patients with advanced solid tumors. A SAKK-SENDO phase Ib study

Project Group Breast Cancer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Presidents:

1 Prof Dr Christoph Rochlitz, Department of Medical Oncology, University Hospital Basel
2 PD Dr Georges Vlastos, Department of Gynecology, Breast Unit, University Hospital Geneva (HUG)

Objectives

The Breast Cancer Project Group (BCPG) aims to facilitate and conduct clinical and translational research in breast cancer and to collaborate with international research groups (i.e. IBCSG, BIG, EORTC). In the currently open trials SAKK 21/08, SAKK 22/99, SAKK 24/09, SAKK 92/08, IBCSG 22-00, IBCSG 24-02, IBCSG 25-02, IBCSG 35-07, IBCSG 36-07, and IBIS-II, these objectives have been reached. In addition, the BCPG keeps its members updated on clinical trials of IBCSG and BIG, and has reached a high visibility of members of the project group in the breast cancer community. It also cultivates excellent international relationships.

After one term as co-president of the BCPG, PD Dr Georges Vlastos, gynecologist from Geneva, did not renew his presidency as the new SAKK project group regulation does not foresee co-presidencies of project groups. Several gynecologists are members of the BCPG and also joined the recently established working group gynecological cancers.

Future objectives of the BCPG are the continuation of clinical trial activities using drugs as the primary intervention, but also an extension to other interventions and endpoints such as quality of life aspects in the SAKK 26/10 and SAKK 24/09 studies, health economic issues in the SAKK 24/09 trial, radiotherapy trials such as IBCSG-38-10, and randomized surgical interventions.

Activities

In 2010, a total of 243 patients were included in clinical trials with a focus on breast cancers (83 SAKK, 160 IBCSG trials), which corresponds to an increase of accrual by 21,5 % compared to 2009.

Trials Activated in 2010

SAKK 24/09 trial | *Safety and tolerability of bevacizumab plus paclitaxel vs. bevacizumab plus metronomic cyclophosphamide and capecitabine as first-line therapy in patients with HER2-negative metastatic or locally recurrent breast cancer. A multicenter, randomized phase III trial*

The aim of this trial is the establishment of a new anti-angiogenetic regimen with equal efficacy but lower toxicity than the «standard» paclitaxel/bevacizumab regimen. The trial was activated by Swissmedic in July 2010, and by the end of the year, nine patients have been included.

SAKK 21/08 trial | *Fulvestrant with or without AZD6244, a mitogen-activated protein kinase kinase (MEK) 1/2 inhibitor, in advanced stage breast cancer progressing after aromatase inhibitor: a randomized placebo-controlled double-blind phase II trial*

The primary objective of the trial is to assess the activity of the combination fulvestrant and AZD6244 in patients progressing after first line aromatase inhibitors. This trial is conducted in collaboration with a Belgian cooperative group. The trial was activated by Swissmedic in November 2010, and by the end of the year, three patients have been included.

Strategic elements for the next two years

In the next two years, the group will focus on the following strategic elements:

– To facilitate and conduct clinical and translational research in breast cancer
– To focus on metastatic breast cancer
– To study triple negative, metastatic breast cancer
– To develop non-drug trials
– To collaborate with international research groups
– To involve more, and especially younger, members of the group in the design and execution of new trials
– To extend collaboration with oncologists and gynecologists working in non-acedemic centers

Portfolio Plan

These protocols are in preparation by the group:

SAKK 22/10 | *Pertuzumab plus trastuzumab/chemotherapy*

SAKK 26/10 | *Introducing recurrence score with circumspection: An observational study in Switzerland (IRS)*

The primary objective of the trial is to assess the influence of molecular tests such as OncotypeDX, RISK-25 and proliferation markers on chemotherapy decisions in the adjuvant treatment of women with ER/PR-positive disease. The proposal was accepted by the SAKK board in December 2010.

IBCSG 38-10 | *A randomized phase III study of radiation doses and fractionation schedules for ductal carcinoma in situ (DCIS)*

Decision by the SAKK board to proceed to final assessment is expected in January 2011.

IBCSG 39/11 (SPRINT) | *Phase II epirubicin alone vs. epirubicin plus PARP inhibitor iniparib*

Collaboration with/participation in other groups

Members of the BCPG are also active within the following national and international breast cancer research groups:

- International Breast Cancer Study Group IBCSG
- Breast International Group BIG
- German Breast Group GBG
- Arbeitsgemeinschaft Gynäkologische Onkologie AGO

Project Group Gastrointestinal Cancer

President:
Prof Dr Markus M. Borner, Clinical Research Unit of the Oncology Department, Inselspital, University Hospital Bern & Oncology Unit, Spitalzentrum Biel

Objectives

Gastrointestinal cancer is a very heterogeneous group of tumor entities. On one side of the spectrum are diseases such as GIST that are well defined on a molecular level and addicted to specific oncogenic pathways. Here, the promise of molecular therapy is already being fulfilled. On the other side of the spectrum, treatment options are still dismal in most gastrointestinal carcinomas due to the polyclonal nature of the disease and molecular targets are urgently needed, for example in metastatic pancreatic cancer. The group aims at using current knowledge on molecular biology to design smart trials which integrate prognostic and predictive factors, targeted drugs and the collection of further molecular information. Examples are the trials in GIST, in esophageal cancer, hepatocellular carcinoma (HCC) or rectal cancer.

Wherever possible, the conduct of phase III trials should be favored and successful recent examples are the trials SAKK 75/08 in esophageal cancer and SAKK 41/06 in colon cancer. The latter is also an example of an evolving new role of SAKK trials to provide data on socioeconomic issues and the pattern of care in Switzerland. Keyplayers of the Swiss health system such as Santésuisse have recognized SAKK as a partner to obtain important information about the cost effectiveness of specific oncological interventions such as bevacizumab maintenance treatment in metastatic colon cancer (SAKK 41/06). Finally, the group wants to help introducing novel treatment approaches in Switzerland by setting up operational procedures in the context of clinical trials. Examples are chemoembolization or radiotherapy for HCC.

Activities

Trials activated in 2010

SAKK 75/08 | *Multimodal therapy with and without cetuximab in patients with locally advanced esophageal carcinoma. An open-label phase III trial*

SAKK 77/09 | *A phase I open label/phase II randomized, double-blind, multicenter trial investigating the combination of everolimus and TransArterial ChemoEmbolisation (TACE) with doxorubicin in patients with hepatocellular carcinoma eligible for TACE*

Strategic elements for the next two years

Rectal cancer has been identified as a tumor entity where rapid accrual is possible in Switzerland. Thus the development of follow-up protocols for SAKK 41/07 and 41/08 is a priority. The collaboration with Santésuisse for SAKK 41/06 is exemplary for its possible health-economical impact besides other clinical research questions. To extend this concept on other important tumor situations seems to be relevant and attractive also in view of the current health care discussions. To live up to the ambitious accrual goal, all efforts have to be made to stimulate active participation not only by the established SAKK centers but also by private clinics, smaller hospitals, and oncologists in private practice. This gives the opportunity to think of models, how SAKK can provide support for decentralized trial activites. Another priority of the group are studies in pancreatic cancer, as progress in this field is painfully slow.

Portfolio Plan

These protocols are in preparation by the group:

SAKK 41/10 | *Erbitux Mono 1st line in elderly followed by combination with capecitabine upon progression*

EORTC 40071 | *Randomized phase II study of lapatinib in combination with ECF/X chemotherapy in unresectable gastric cancer*

Collaboration with/participation in other groups

The group is well connected internationally. In recent years, the center of Budapest, Hungary (Prof Dr G. Bodoky) has contributed very actively to the accrual of the group. The SAKK trial 75/08 in esophageal cancer is the result of a successful collaboration with German centers led by Prof Dr M. Stahl. Also, the European Organisation for Research and Treatment of Cancer (EORTC) is an important international partner for the SAKK. The fact that PD Dr A. Roth has been elected president of the EORTC Gastrointestinal Group will further strengthen this tie. Recent examples are protocols for metastatic Her1 or Her2 positive gastric cancer and an eagerly expected protocol for the adjuvant multimodal treatment of pancreatic cancer. One further important step, which will help transatlantic connections, was to recruit Prof Dr H.-J. Lenz (USC Norris Comprehensive Cancer Center, Los Angeles, USA) as an international expert to the group. We are very happy that he accepted this task. His background in translational research and his knowledge on the activities of the American cooperative groups will be most welcomed by the group.

Personal note

After six years I stepped down as president of the group. It was a very satisfying task for me and I would like to thank the members for their stimulating and always cordial interactions. I am very proud to hand over the group to the new president Dr Michael Montemurro, Centre University Hospital Lausanne, in good shape. I would like to wish Michael as much satisfaction and pleasure as I had with the group. Thank you all!

Project Group Leukemia

President:
PD Dr Yves Chalandon, Hematology Service, University Hospital Geneva (HUG)

Objectives

We undertake clinical studies covering the main topics in acute and chronic leukemia, however currently no trials in low risk myelodysplasia (MDS) and myeloproliferative disorders (MPD). The project group collaborates with international study groups in developing and performing phase II–III trials. But still, more participation of Swiss members in international cooperative groups is desirable. Phase I–II trials testing new compounds and combinations are being developed; the main goal is to develop SAKK trials in specific niches, for example hairy cell leukemia, AML relapse, CLL relapse, frail or elderly patients suffering from leukemia. The project group also participates in international working groups.

We have established a platform for younger clinical researchers, and some younger investigators are now involved in SAKK trials. The group will check to take over the lead in Phase III trials. The objective to have active members working in the field of acute and chronic leukemia has been partially achieved as still too few members are active (around 10–15). It is desirable that smaller centers participating in SAKK become more involved in the studies of the Project Group Leukemia and particularly in chronic leukemia trials (partially achieved) to still improve the accrual in trials. In order to improve our capacity to include patients in trials of chronic leukemia, we are evaluating a possibility of collaboration with private practitioners in onco-hematology.

Activities

Trials activated in 2010

SAKK 65 / 08 | *In collaboration with the Phase I project group and the lymphoma project group: Synergistic targeting of the endoplasmic reticulum stress response with nelfinavir and bortezomib: a phase I dose escalation trial in advanced hematologic malignancies*

The objective of the trial is to assess tolerability and toxicity of the induction of UPR (unfolded protein response) activity by nelfinavir in combination with bortezomib in patients with advanced hematopoetic malignancies and to establish the recommended dose for phase II. The trial was activated in July 2010.

HOVON 102 / SAKK 30 / 10 (follow up HOVON 92 / SAKK 30 / 08) | *Randomized study with a run-in feasibility phase to assess the added value of clofarabine in combination with standard remission-induction chemotherapy in patients aged 18–65 years with previously untreated acute myeloid leukemia (AML) or myelodysplasia (MDS) (RAEB with IPSS ≥ 1.5)*

The trial is divided into two parts. The main objective of part A is to determine the feasibility of clofarabine when given at three possible dose levels together with standard induction cycles I and II in patients with AML / RAEB with IPSS ≥ 1.5 in a prospective comparison to standard induction cycles I and II without clofarabine. The main objective of part B will be to evaluate the effect of clofarabine at the selected feasible dose level when combined with remission induction chemotherapy cycles I and II with regards to clinical outcome («event-free survival») in comparison to remission induction cycles I and II with no addition of clofarabine in a phase III study. The trial was activated in September 2010.

Strategic elements for the next two years

- To improve the accrual of chronic leukemia patients in trials (with help of the smaller SAKK centers to initiate the trials, find a solution to interact with private practitioners in hemato-oncology and to make the inclusion of their patients in SAKK trials possible)
- To set up a trial for low risk MDS patients
- To develop phase II trials for patients with acute leukemia unfit for intensive chemotherapy or for elderly patients with new drugs targeted therapy (in combination with low dose sequential chemotherapy) or vaccines

- To develop phase II trials in specific niches such as hairy cell leukemia, relapsed AML or CLL
- To stimulate translational research projects (prognostic Minimal Residual Disease MRD) as well as study of leukemic stem cells, leukemogenesis, genomic and proteomic) as this has been insufficiently done for the last years. We need to increase collaboration with research laboratories
- To improve the input of SAKK participation in international phase III trials

Portfolio Plan

These protocols are in preparation by the group:

EBMT RIC-MUD AML | *A Randomized Phase III study comparing conventional chemotherapy to low dose total body irradiation-based conditioning and hematopoietic cell transplantation from related and unrelated donors as consolidation therapy for older patients with AML in first complete remission*

The objective is to evaluate leukemia-free survival after allogeneic hematopoietic stem cell transplantation in AML/RAEB in complete remission using matched or unrelated donors in comparison to conventional chemotherapy.

The initiation of the trial in Switzerland was delayed due to a new major amendment to the trial protocol and the trial will be activated in 2011.

PROMYSE | This study is a European registry study for APL relapsing patients under the auspices of the European LeukemiaNet (ELN). This is already running in seven countries in Europe and the Leukemia Project Group is going to join this study in 2011. As different treatment options for relapsed APL are now available, it is necessary to assess their efficacy and safety in order to assess the most suitable therapeutic strategies for various APL patient groups. Given the rarity of this disease and the limited number of patients relapsing after first-line therapy, it is essential that such a trial is implemented on a pan-European basis to ensure a sufficient number of patients will be included in a reasonable period of time.

SAKK 31/10 | *High dose lenalidomide in combination with sorafenib and nelfinavir in elderly and unfit patients with de novo acute myeloid leukemia: a phase I/II trial.*

The objective of the phase I part of the study is to determine the MTD, dose limiting toxicities and tentatively recommended dose for high dose lenalidomide (50 mg/d) combined with nelfinavir and sorafenib in patients with AML.

The objective of the phase II part is to determine the efficacy and safety of this combination induction regimen at the recommended dose, followed by a lenalidomide maintenance phase in responding patients.

HOVON 103 (follow up HOVON 81) | *A program of randomized phase II multicenter studies to assess the tolerability and efficacy of the addition of new drugs to standard induction therapy in AML and RAEB ≥ 65 years and very poor risk AML ≥ 18 years.*

This is a master protocol that will try to investigate new drugs that act in combination with standard chemotherapy in elderly AML. The trial will be divided in two parts. For part A of the study (if applicable): 1. To assess the safety and tolerability of drug X added to standard induction chemotherapy for AML (frequency and severity of toxicities and the durations of neutropenia and thrombocytopenia) and select a feasible dose level for part B. 2. To assess in a randomized comparison the effect of drug X on the CR rate.

For part B of the study: 1. To assess the safety and tolerability of drug X added to standard induction chemotherapy for AML (frequency and severity of toxicities and the durations of neutropenia and thrombocytopenia) with regards to the selected dose level of drug X. 2. To assess in a randomized comparison the effect of drug X on the CR rate.

CML V, Chronic Myeloid Leukemia | A trial with the German Study Group which should follow the CML IV protocol. The trial is still under discussion in the project group and in the German Study Group.

GRAALL 2012 (follow up GRAALL 2005) | This will be the follow-up study for ALL patients (T-ALL, B-ALL, Ph+ B-ALL) in collaboration with the French groups LALA and GOELAMS and the Belgian group (the GRAALL group is the collaborative group including GOELAMS, LALA and SAKK groups).

The trial is under discussion in the GRAALL group and should be ready to start in 2012.

Follow up trial of SAKK 30/07 | An AML trial for frail elderly AML patients is under development.
Primary objective: to compare either 5-Azacytidine with standard of care (either best supportive care or low dose Ara-C) or the new drug sapacitabine with standard of care. A follow-up in HCL is under discussion.

Collaboration with / participation in other groups

The Leukemia Project Group collaborates with the Lymphoma Project Group and the Project Group New Anticancer Drugs within the SAKK and with the following other groups:

- Laboratory group (molecular diagnostic) SMH, Swiss Molecular Hematology / Oncology
- The Dutch HOVON group in AML
- The collaborative group GRAALL (Group for Research in Adult Acute Lymphoblastic Leukemia) including the French groups GOELAMS and LALA, Belgium in ALL
- The German CLL Study Group (GCLLSG) in CLL
- The German CML Study Group (GCMLSG) in CML
- The European APL group
- The European LeukemiaNet (ELN)
- The European Group for Blood and Marrow Transplantation (EBMT)

Project Group Lung Cancer


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Presidents:

1 PD Dr Miklos Pless, Department of Medical Oncology and Tumor Center, Cantonal Hospital Winterthur
2 Prof Dr Walter Weder, Division of Thoracic Surgery, University Hospital Zurich

Objectives

- The Lung Cancer Project Group creates and organizes trials for patient care in order to treat as many Non-Small Cell Lung Cancer (NSCLC) patients in trials (stage IV) as possible
- It establishes a network of Swiss lung cancer centers with multidisciplinary thoracic capacity (stage IIIB / IIIA), as well as a basis for translational research (tissue banking)
- One research focus is the multidisciplinary treatment of malignant mesothelioma
- The group has become an attractive partner for pharmaceutical companies with interesting compounds, and helps to advance the career of young oncologists
- One important objective is to promote the careers of young investigators by supporting the take-over of the principal investigator function in SAKK Lung Cancer protocols

Activities

Activated trials in 2010

SAKK 15/08, SCLC | *Carboplatin and paclitaxel plus ASA404 as first line chemotherapy for extensive-stage small-cell lung cancer (SCLC). A phase II trial*
The main objective is the efficacy and feasibility of this combination in SCLC. The trial opened in April and 16 patients have been enrolled in 2010.

SAKK 16/08, NSCLC | *Preoperative chemo-radiotherapy combined with concomitant cetuximab in non-small cell lung cancer (NSCLC) patients with IIIB disease. A multicenter phase II trial*

The objective of this trial is to evaluate activity and safety of sequential neoadjuvant chemo-radiotherapy with concomitant targeted therapy of cetuximab in operable stage IIIB NSCLC patients. Seven patients were included since June 2010.

SAKK 19/09, NSCLC | *Pemetrexed, cisplatin and bevacizumab, or erlotinib and bevacizumab for metastatic adenocarcinoma of the lung according to EGFR mutation status: a multicenter phase II study including biopsy at progression (BIOPRO trial)*

The main objective is to demonstrate that tailored therapy, according to tumor histology and EGFR mutation status, and the introduction of novel drug combinations in the frontline treatment of advanced NSCLC is promising for further investigation.

Strategic elements for the next two years

To complete our portfolio of studies by

- joining a new adjuvant study for early stage NSCLC
- starting a new trial in SCLC, extensive disease
- possibly finding other interesting areas of research (e.g. mesothelioma stage IV, SCLC LD, inoperable stage IIIB NSCLC etc.)

To start working on follow-up protocols in our core indications:

- stage IIIA/N2, follow-up for SAKK 16/00
- operable Stage IIIB, follow-up for SAKK 16/08
- stage IV NSCLC, follow-up for SAKK 19/09

To strengthen the cooperation with other cooperative groups, e.g. the Belgian group in Leuven or the German group in Freiburg i.B., and to find new international partners

- To support the European Thoracic Oncology Platform (ETOP)
- To establish a translational research network, evaluating biological questions with material from our previous trials
- To establish a tissue bank for lung cancer

Collaborations with / participation in other groups:

- Freiburg im Breisgau
- Leuven (Belgium)
- European Thoracic Oncology Platform ETOP

Project Group Lymphoma

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

Objectives

The Lymphoma Project Group's main objectives are to bring together onco-hematologists and other specialists involved and interested in the management of lymphoma / myeloma patients, to improve the cure and the treatment of patients with lymphoma, by developing and leading some innovative clinical trials accessible to as many patients as possible in Switzerland. Another objective of the Project Group Lymphoma is to establish and maintain an active scientific collaboration with other international collaborative groups, such as the HD group in Germany and the EMN group in Europe. The project group should be a platform for young clinical investigators and should stimulate and promote translational research for a better understanding of lymphoid malignancies with the aim to improve the treatment of the patients and to personalize the cure depending on the different subgroups.

Activities

Trials Activated in 2010

HD 16 | *Treatment optimization trial in the first-line treatment of early stage Hodgkin lymphoma; treatment stratification by means of FDG-PET*

The aim of the HD16 trial is to individualize treatment for each patient by adapting it to early response after two cycles of chemotherapy ABVD (adriamycin, bleomycin, vinblastine and dacarbazine). A further aim of the trial is to assess the efficacy of standard therapy in the subgroups of PET-positive (S+ and E+) and PET-negative patients (S-).

Strategic elements for the next two years

The project group will continue to focus on the collaborations with other international collaborative groups as key element for the immediate future. These collaborations will have to produce sound clinical studies in a very competitive field while allowing a high international visibility for the SAKK.

A most important problem of the Lymphoma PG during the past year has been the relevant reduction in patient accrual. This is largely dependent on the closure of the trials SAKK 36/06 and 38/07 on mantle cell lymphoma and diffuse large cell lymphoma respectively and to the persistent lack of a new follicular lymphoma study.

The most important element for the immediate future is to initiate again a trial for follicular lymphoma patients. Indeed, the SAKK 35/10 study of rituximab plus lenalidomide versus rituximab monotherapy in untreated follicular lymphoma patients is approved by the Ethics Committee in the Canton of Ticino (the lead EC) and by Swissmedic.

This open-label, multicenter, randomized phase II trial will be conducted in collaboration with the Nordic Lymphoma Group. The long-term results of the pivotal SAKK 35/98 study have been published last year (Martinelli et al., 2010, Journal of Clinical Oncology) and obtained enormous interest of the scientific community confirming that the development of chemotherapy-deferral strategies in the front-line treatment of follicular lymphoma is a worthwhile objective.

SAKK 39/10 is under development and aims to treat relapsed myeloma patients after failure of the lenalidomide/dexamethasone treatment. Also, in this case a new, innovative way for the management of this type of patients is proposed with the use of nelfinavir and lenalidomide.

Another important objective is to set up a fruitful collaboration with the International Extranodal Lymphoma Study Group (IELSG) which is running several studies in extranodal lymphomas. Indeed, a general agreement for a regular collaboration between SAKK and IELSG has been reached.

The HD 17 trial for early unfavourable Hodgkin Lymphoma is also a new project for 2011. The IELSG-32 randomised study on the front-line therapy of primary CNS lymphoma is planned to be activated in 2011. The development of the next trial in diffuse large B-cell lymphoma is in advanced planning stage. We are considering joining a large international randomized phase III trial launched by UK Cancer Research (REMo). In this study, patients with the diagnosis of DLBCL will either be treated with 6 x R-CHOP-21 or the same protocol including bortezomib. There are not many academic groups performing innovative trials in DLBCL and this is one of the few that asks an important research question (addition of bortezomib) and prospectively collects tissue samples for gene expression analysis.

Portfolio Plan

These protocols are in preparation by the group:

SAKK 35/10 | *Rituximab plus lenalidomide or rituximab monotherapy for untreated patients with follicular lymphoma in need of therapy. A randomized, open-label, multicentre phase II trial*

EMN-02/HOVON 95 MM | *A randomized phase III study to compare bortezomib, melphalan, prednisone (VMP) with high dose melphalan followed by bortezomib, lenalidomide, dexamethasone (VRD) consolidation and lenalidomide maintenance in patients with newly diagnosed multiple myeloma*

Collaboration with/participation in other groups

- While, as suggested by the SAKK Board, collaboration with the Intergroupe Francophone du Myélome (IFM) has been discontinued in 2010, the project group has begun to set up a collaboration with the European Myeloma Network with the aim to actively participate in EMN trials
- German Hodgkin Study Group (HD trials)
- Nordic Lymphoma group (follicular lymphoma trial)
- European Mantle Cell Lymphoma Network
- International Extranodal Lymphoma Study Group (IELSG)

Project Group New Anticancer Drugs/ Phase I Trials

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

Objectives

The primary aim of the project group is to increase the active participation in Phase I trials and to get new drugs to be tested by SAKK in Phase II trials; the group also aims to set up within the SAKK a network of Phase I prinicipal investigators who have contacts with drug companies involved in drug development to enlarge the SAKK portfolio. SAKK and SENDO have established a collaboration in order to increase and improve the involvement of selected SAKK centers in early clinical trials and to support the implementation of investigator promoted studies.

Activities

Trials Activated in 2010

SAKK 65/08 | *Synergistic targeting of the ER stress response with nelfinavir and bortezomib: a phase I dose escalation trial in advanced hematologic malignancies*
This trial has been developed in collaboration with the Project Group Leukemia and the Project Group Lymphoma. Patients are being accrued in selected centers.

SO95ST1902 | *Phase I dose finding and pharmacokinetic study of daily administrations of the intravenous camptothecin Namitecan (ST1968) in patients with refractory or recurrent solid tumors. A SAKK SENDO phase I study*
This trial is developed with SENDO and will be conducted in two centers in Switzerland and in one center in Italy.

Collaboration with / participation in other groups

- Project Group Leukemia
- Project Group Lymphoma
- SENDO Southern Europe New Drugs Organization

Project Group Urogenital Tumors


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Presidents:
1 PD Dr Silke Gillessen, Department of Internal Medicine Division, Divison Medical Oncology-Hematology, Cantonal Hospital St.Gallen
2 Prof Dr George Thalmann, Urology Department, University Hospital Berne

Objectives

- The Project Group Urogenital Tumors (PGU) aims to conduct clinical and translational research in the whole field of urogenital tumors, with a special focus on prostate cancer involving all disciplines interested in the topic
- The integration of all disciplines involved in the treatment of urogenital cancers is warranted and still ongoing. There was remarkably more active input from radio-oncologists during the last year and one radio-oncological trial (SAKK 09/10) will be opened in the beginning of 2011
- We hope to further enhance the interest of young urologists in our group, and therefore develop more trials of urological interest
- In the field of prostate cancer, large studies should be performed by the PGU
- The PGU aims to collaborate with international research groups like the Medical Research Council (MRC) or the German Group for Testicular Cancer

Activities

Trials Activated in 2010

SAKK 08/09 | *Metformin in castration resistant prostate cancer: A multicenter phase II trial*

The main objective of the trial is the assessment of activity and safety of metformin as first-line therapy in non-rapidly progressive castration resistant prostate cancer (CRPC). The trial has been activated in November 2010 and by the end of the year, two patients have been included.

STAMPEDE | *Systemic therapy in advancing or metastatic prostate cancer: Evaluation of drug efficacy. A 5-stage multi-arm randomised controlled trial*

The overall primary outcome measure for the trial is overall survival (all-cause mortality).

Strategic elements for the next two years

- To focus on prostate cancer in early asymptomatic and oligosymptomatic slowly progressing castration resistant disease before chemotherapy and in second line therapy after docetaxel including maintenance therapy
- To intensify translational research together with the pathologists and other interested research groups working in the field of urogenital tumors in general and again focused on prostate cancer
- To motivate young urologists, medical oncologists and radio-oncologists to join the group and facilitate their start in designing and conducting trials
- To ameliorate the multidisciplinary approach in the field of urogenital tumors
- To strengthen the collaboration with international groups like the Medical Research Council MRC and other international centers

Portfolio Plan

According to the above mentioned strategy, we opened the successor trial of SAKK 08/08 called SAKK 08/09 (using metformin instead of everolimus and having stricter inclusion criteria) and a successor trial of SAKK 08/07 is under discussion (maintenance therapy with a CYP-17 inhibitor after first line therapy with a taxane).

After final evaluation of SAKK 08/07 we have to decide if further evaluation of the combination of docetaxel and cetuximab in a first line setting as randomized phase III trial (docetaxel +/-cetuximab) is of interest for us and the company. Translational research could be helpful to define biomarkers for stratification. For a phase III trial we would need international collaboration.

The trial SAKK 09/10 (dose intensified salvage radiotherapy in biochemically relapsed prostate cancer without macroscopic disease. A randomized phase III trial) was activated in January 2011 and is led by the radio-oncologists. Additionally, trials in seminoma Stage II A and B and a follow-up trial for patients with testicular cancer have been proposed.

Collaboration with / participation in other groups

The STAMPEDE trial is conducted in collaboration with the MRC. More intensive collaboration with the MRC is hopefully made possible by our external advisor Dr Thomas Powles. A potential collaboration with the German Testicular Cancer Group is planned in the field of follow up of testicular cancer patients and in seminoma patients with stage II A and B.

The maintenance trial with a CYP-17 inhibitor is planned to be performed in collaboration with other selected centers, experienced in the treatment of metastatic prostate cancer.

Section Pathology

President:
Prof Dr Holger Moch, Department Pathology,
University Hospital Zurich

Short Introduction

The section Pathology aims to design and conduct translational research in the field of clinical trials. It functions as a platform to promote multicenter trials in the pathology community. Further, the section is active in the following areas:

- Quality assurance of clinical trials regarding pathology diagnoses
- Review of initial pathology diagnoses; the goal of such a review is quality assurance
- Establishment of novel predictive tests, e.g. KRAS testing in colorectal cancer or BRAF-testing in melanoma
- Translational research requires tissue banking; pathologists are involved in collection of biomaterial and establishment of biobanks

Activities 2010

The Section Pathology is involved in more than 20 SAKK trials. The section members also play an important role in the activities of the IBCSG, both on a practical level by contributing patient material and on an intellectual and leadership level. Further, section members continue to enroll patient material in earlier studies and in new SAKK trials. Such trials include activities in the Lung Cancer Project Group (SAKK 16/08, SAKK 17/04), Lymphoma (SAKK 38/07, SAKK 36/06), Urogenital Tumors (SAKK 08/07, SAKK 08/08) and the Working Groups Melanoma (SAKK 50/07), Head and Neck Cancer (SAKK 10/94) and others. These activities include the collection of biomaterial, translational research and predictive tests.

Outlook

- Involvement of pathologists in the early phases of protocol development
- Improvement of budgeting, implementation and monitoring of pathology activities in clinical trials
- Activities according to the SAKK procedures for pathology investigations and translational research
- Establishment of the SAKK rules for translational research and biobanking

Section Radio-Oncology

President:
PD Dr Ludwig Plasswilm, Department of Radio-Oncology, Cantonal Hospital St. Gallen

Short introduction
The Section Radio-Oncology aims to design and develop new trials in the field of radiotherapy. It functions as a platform to promote new multicenter trials in the SAKK community. Quality assurance becomes a main issue.

Main activities 2010
In 2010, the members of the SAKK Section Radio-Oncology focused mainly on possible opportunities to increase the activities of radiation oncology within SAKK trials. The section is involved in many SAKK trials. Section members continue to enrol patients in ongoing studies. Such trials include activities in the gastrointestinal group, the lung cancer group, lymphoma, urogenital tumors and others. In general, the completion of patient forms requires the engagement of many radiation oncologists in a wide range of ongoing trials.

In 2010, the section was able to start with a quality assurance (QA) program within a new phase III trial on locally advanced esophageal carcinoma (SAKK 75/08). This QA procedure is based on the review of radiotherapy documents of individual patients randomized in that trial. A new internet-based platform was created to enable the safe and fast transfer of individual radio-oncology plans between the treating centers and the center responsible for the review procedure.

In cooperation with the group of urogenital tumors, the Section Radio-Oncology was able to develop a new protocol on dose escalation in radiation therapy of biochemically relapsed prostate cancer (SAKK 09/10). The trial objectives are the assessment of tumor control, toxicity and quality of life after dose-intensified salvage radiotherapy. Patient accrual of this randomized phase III trial will start 2011.

Outlook
- To involve the radiation oncologists in the early phase of trial development
- To implement new trials focusing on radiation oncology related questions
- To establish statements of the Section Radio-Oncology on all new SAKK trials with any relation to radiation oncology
- To establish radiotherapy quality assurance procedures for all new SAKK trials when radiotherapy is part of the protocol

Network for Cancer Predisposition Testing and Counseling (CPTC)


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Presidents:
1 PD Dr Pierre O. Chappuis, Division of Oncology, Division of Genetic Medicine, University Hospitals of Geneva (HUG)
2 Prof Dr André-Pascal Sappino, Division of Oncology, University Hospitals of Geneva (HUG)

Objectives of the Network

The aims of the Network for CPTC are:
- To harmonize the clinical practice of counseling and management of at-risk individuals according to international guidelines
- To collect clinical and molecular data from families with inherited cancer-predisposing syndromes
- To consolidate the collaboration with molecular geneticists in charge of cancer predisposition testing
- To participate in trials evaluating the impact of surveillance and risk reduction strategies
- To inform and educate health professionals and the lay community on predictive oncology

Activities 2010 and Outlook

More than 450 new families with familial/hereditary cancer syndromes have been managed in Switzerland this year. Seventeen centers located in 10 cities are in charge of genetic counselling and evaluation for cancer predisposition testing according to the Swiss regulation (KVL/OPAS/OPre art. 12d, let. f).

Swiss guidelines for genetic counselling referral for individuals with personal and/or family history of breast/ovarian cancer have been prepared. These guidelines will help clinicians to identify cases where a familial aggregation or a syndrome of hereditary breast/ovarian cancer should be suspected, and an adequate management could be proposed. These guidelines will be submitted for publication in several Swiss medical journals.

Since 2004, 60 women have been included in the ongoing IBIS II Prevention and DCIS randomized double blind control trials (evaluation of anastrozole as an effective method of preventing breast cancer in postmenopausal women at increased risk of the disease).

Based on data collected by members of the Network, a molecular research project entitled «Comprehensive screening of a panel of breast cancer susceptibility genes in BRCA1/BRCA2-mutation negative families» has been granted this year by the SAKK and the Swiss Cancer League. The aim of this project is to evaluate the incidence of germline alterations in a set of candidate breast cancer predisposing genes in highly selected non-BRCA1/BRCA2-related breast cancer families using a customized array-based high-throughput resequencing strategy.

The aim of a genetic counselor's PhD thesis is to get an overview of the epidemiology of BRCA1 and BRCA2 germline alterations in Switzerland: genotype-phenotype association, ancestral mutation, value of available prediction models of constitutional mutations.

In June 2010, Prof Dr André Sappino stepped down from his role as co-president of the network. We thank him for his commitment during the past years.

Network for Outcomes Research


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President:

1 Prof Dr Bernhard Pestalozzi, Department of Oncology, University Hospital Zurich

Vice-President:

2 Prof Dr Thomas Szucs, European Center of Pharmaceutical Medicine, University of Basel, and Institute of Social and Preventive Medicine, University of Zurich

Network Activities in 2010 and Outlook

A key activity of the Network is to perform health-economic analyses (HEA) alongside clinical trials. Although Switzerland has no institution like NICE (National Institute for Health and Clinical Excellence) in the U.K. to evaluate the cost effectiveness of drugs, it becomes more and more important to collect health economic information on newly introduced treatments. In the mid- to long-term, this information will become important for healthcare decision making.

Prospective health economic evaluations were implemented as sub-projects in four SAKK trials and one trial in cooperation with the Central European Society for Anticancer Drug Research CESAR as mentioned below. Data collection procedures and clinical report forms were developed and the preference-based quality of life questionnaire EQ-5D was included. For several studies, data collection and data monitoring is being performed (start July 2010).

Retrospective data collection for some ongoing SAKK trials was continued. For one trial, a protocol amendment was written and accepted in order to cover revised HEA methodology.

The outcomes research study SAKK 89/09 «Delivery of care at the end of life of cancer patients in Switzerland», in collaboration with the insurance company Helsana and four cancer registries, has been approved by the ethical committees of the participating cantons as well as by the «Eidgenössische Expertenkommission für das Berufsgeheimnis in der medizinischen Forschung». To provide the data basis for this study, insurance company and cancer registry data merging will start in 2011.

Two literature-based HEA were published:

1. Joerger M, Matter-Walstra K, Fruh M et al. *Addition of cetuximab to first-line chemotherapy in patients with advanced non-small-cell lung cancer: a cost-utility analysis.* Ann Oncol 2010.
2. Matter-Walstra KW, Dedes KJ, Schwenkglenks M et al. *Trastuzumab beyond progression: a cost-utility analysis.* Ann Oncol 2010.

One new literature-based HEA has been finalised and will be submitted for publication in 2011:
K.M. Matter-Walstra, M. Joerger, U. M. Kühnel, T. Scuzs, B.C. Pestalozzi, M. Schwenkglenks, Cost effectiveness of maintenance pemetrexed in patients with advanced non squamous-cell lung cancer from the perspective of the Swiss health care system.
The study is based on the results of Ciuleanu T, Brodowicz T, Zielinski C et al. «Maintenance pemetrexed plus best supportive care versus placebo plus best supportive care for non-small-cell lung cancer: a randomised, double-blind, phase 3 study». Lancet 2009; 374: 1432-1440, and will address the problem of missing resource use information for best supportive care in cost-effectiveness analyses.

Networking activities

At the semi-annual SAKK meeting in November 2010, Dr Klazien Matter Walstra held a presentation on small area analysis and the potential relevance of this methodology for Switzerland.

Trials involving a health economic analysis

SAKK 35/03 (closed for accrual) | *Comparing two schedules of rituximab maintenance in rituximab-responding patients with untreated, chemotherapy resistant or relapsed follicular lymphoma. A randomized phase III trial*
This trial has a long overall survival and therefore, a two-step economic analysis is planned, which will partially use claims data from insurance companies and will model costs and effects using a life-long time horizon.

SAKK 16/00 (open) | *Preoperative chemoradiotherapy vs. chemotherapy alone in non-small cell lung cancer (NSCLC) patients with mediastinal lymph node metastases (stage IIIA, N2). A randomized prospective phase III trial*
This trial is ongoing and HEA will be performed from a statutory health-insurance perspective, with cost data coming from the patients' insurance companies. An amendment for the revised HEA sub-project is in preparation.

SAKK 77/08 (open) | *Sorafenib alone or in combination with everolimus in patients with unresectable hepatocellular carcinoma. A randomized multicenter phase II trial*
Prospective HEA sub-project included.

SAKK 77/09 (Part II will open in 2011) | *A phase I open label/phase II randomized, double-blind, multicenter trial investigating the combination of everolimus and TransArterial ChemoEmbolisation (TACE) with doxorubicin in patients with hepatocellular carcinoma eligible for TACE*
Prospective HEA sub-project in Phase II included.

SAKK 75/08 (open) | *Multimodal therapy with and without cetuximab in patients with locally advanced esophageal carcinoma. An unblinded, prospectively randomized phase III trial*
Prospective HEA sub-project included.

SAKK 24/09 (open) | *Safety and tolerability of bevacizumab plus paclitaxel vs. bevacizumab plus metronomic cyclophosphamide and capecitabine as first-line therapy in patients with HER2-negative metastatic or locally recurrent breast cancer. A multicenter, randomized phase III trial*
Prospective HEA sub-project included.

SAKK 89/09 (open) | *End-of-life delivery of care patterns in Swiss cancer patients*
Project ongoing.

CEPAC-TDM study (start 2011) | In cooperation with CESAR Central European Society for Anticancer Drug Research. *An open-label, randomized, parallel group study of patients treated with paclitaxel with standard dosing versus pharmacokinetic guided dose adjustment in patients with advanced NSCLC*
Prospective HEA sub-project included.

Collaboration with/participation in other groups

The network initiated a project-level cooperation with different institutions active in the field of cancer, for example with insurance companies and the National Institute for Cancer Epidemiology and Registration (NICER). An intensive collaboration with NICER concerning data merging of cancer registries and other data sources is ongoing.

The network also applied for membership in the Swiss Network for Health Technology Assessment SNHTA. The answer to this request is expected in 2011.

SAKK and Collaborating Groups

Lung Cancers

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Leukemia

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Lymphoma

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Betriebsrechnung 1. Januar bis 31. Dezember (in CHF)	**2010**	**2009**
Betriebsertrag		
Forschungsbeiträge SBF[1]	4 109 180.00	4 019 850.00
Forschungsbeiträge diverse[2]	1 225 200.00	803 600.00
Forschungsbeitrag santésuisse	1 278 960.00	717 062.00
Erträge Industriekooperationen	3 214 106.00	4 126 604.45
Erträge ausländische Studiengruppen	201 234.07	89 910.11
Erträge Krebsbulletin	364 248.00	326 490.00
Spenden, Legate und Erbschaften	165 211.95	57 569.80
Diverse Erträge	446 600.61	287 745.52
Total Betriebsertrag	**11 004 740.63**	**10 428 831.88**
Betriebsaufwand		
Diverser studienbezogener Aufwand	– 1 381 063.85	– 824 010.07
Forschungsbeiträge IBCSG[3]	– 250 000.00	– 250 000.00
Forschungsbeiträge Zentren	– 2 877 736.46	– 3 009 964.17
Reise- und Repräsentationsaufwand	– 201 215.30	– 167 700.44
Sonstiger Betriebsaufwand	– 135 061.63	– 192 479.10
Total Betriebsaufwand	**– 4 845 077.24**	**– 4 444 153.78**
Zwischenergebnis 1	6 159 663.39	5 984 678.10
Koordinativer Aufwand		
Personalaufwand	– 5 805 948.34	– 5 016 747.44
Sonstiger Koordinationsaufwand	– 1 132 768.56	– 1 042 005.77
Total koordinativer Aufwand	**– 6 938 716.90**	**– 6 058 753.21**
Zwischenergebnis 2	– 779 053.51	– 74 075.11
Finanzergebnis		
Finanzertrag	42 433.03	18 536.98
Finanzaufwand	– 60 624.07	– 4 695.73
Total Finanzergebnis	**– 18 191.04**	**13 841.25**
Zwischenergebnis 3	– 797 244.55	– 60 233.86
Fondsveränderungen		
Auflösung Rückstellungen	210.00	3 133.00
Auflösung Fonds	38 510.00	30 568.00
Total Fondsveränderungen	**38 720.00**	**33 701.00**
Zwischenergebnis 4	– 758 524.55	– 26 532.86
Periodenfremder Erfolg		
Periodenfremder Ertrag	11 568.78	19 736.66
Periodenfremder Aufwand	– 638.85	– 126 850.80
Total Periodenfremder Erfolg	**10 929.93**	**– 107 114.14**
Vereinsergebnis	**– 747 594.62**	**– 133 647.00**

1 Staatssekretariat für Bildung und Forschung SBF

2 Krebsliga Schweiz KLS / Stiftung Krebsforschung Schweiz KFS / Schweizerische Stiftung für Klinische Krebsforschung SSKK

3 International Breast Cancer Study Group IBCSG

SAKK Industriepool 2010

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