SAKK

Rapporto annuale 2007

SPOG
VSKR

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

Indice

Redazione: Ruth Kellenberger
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Editoriale

Attualità 2007

Del Prof. Richard Hermann | Presidente SAKK

L'anno 2007 verrà ricordato come un momento importante nella storia del SAKK. Tre sono stati gli avvenimenti più significativi:

- la semplificazione delle strutture
- l'ammissione di nuovi membri
- la revisione degli statuti

Inoltre, ed è una cosa naturalmente vitale per noi, abbiamo raggiunto l'accordo per il sostegno finanziario da parte della Confederazione per altri 4 anni.

La semplificazione delle strutture e lo scioglimento di fatto dell'Istituto Svizzero di Ricerca Applicata sul Cancro (SIAK) semplificano il metodo di lavoro e i processi nella ricerca clinica sul cancro in Svizzera. C'è un minore dispendio in termini lavorativi per direttivi, comitati e commissioni speciali. Il nuovo assetto e il nuovo posizionamento di strutture sovraordinate devono essere definiti nell'anno 2008.

L'iniziativa del SAKK «Centri intermedi» ha riscosso molto successo. Dopo una gara d'appalto, sette nuovi membri del SAKK possono costruire, con il sostegno della Lega svizzera contro il cancro, una propria infrastruttura per la ricerca clinica sui tumori nella propria regione e nel relativo ospedale. Il SAKK prevede pertanto un sostanziale contributo nel reclutamento di pazienti per gli studi in corso e per quelli futuri. Il numero di pazienti coinvolti negli studi SAKK è inoltre un indicatore importante, anche se non il solo, per un'attività di successo dell'associazione.

È stato necessario adeguare gli statuti dell'associazione per vari motivi. In particolare i poteri decisionali degli organi dell'associazione dovevano essere adattati ai principi della direzione aziendale (corporate governance) per le organizzazioni no profit della Svizzera (Swiss NPO Code) ed era necessaria una nuova regolamentazione per la possibilità di accettazione di nuovi soci (v. sopra). Ora è ufficialmente possibile accettare i centri stranieri come membri associati. Non ultimo, è stata reintrodotta la limitazione del mandato del Presidente a due periodi di 3 anni ciascuno.

Il SAKK ha un nuovo consiglio direttivo che è stato eletto nel novembre del 2007 e che incomincia il suo lavoro all'inizio del 2008. Tale direttivo costituisce il più alto comitato dirigente del SAKK, le cui responsabilità ed i cui compiti sono descritti negli statuti ed illustrati sul sito www.sakk.ch.

Trovo di particolare importanza la definizione di una strategia e la delibera sulle attività di ricerca. I membri del direttivo hanno pertanto compiti importanti. Ho fiducia nel fatto che il nuovo direttivo si metta subito al lavoro e che dia un contributo importante allo sviluppo ulteriore del SAKK.

Colgo l'occasione per ringraziare tutte le persone che nel 2007 hanno reso possibile lo sviluppo che ho appena descritto, grazie al grande impegno profuso che va al di là dei meri compiti quotidiani. È sempre molto stimolante lavorare con persone che perseguono con impegno ed entusiasmo un obiettivo prefisso.

Ora potremmo pensare che l'anno nuovo porti con sé una maggiore tranquillità. Tuttavia, ci sono già diversi compiti che devono essere intrapresi con urgenza. In generale, il reclutamento di pazienti nei nostri studi non ha ancora raggiunto livelli soddisfacenti. Per migliorarlo, dobbiamo lavorare ulteriormente sulla motivazione dei nostri membri. Vogliamo sottolineare ancora una volta che noi facciamo ricerca cooperativa, vale a dire che il nostro dare e il nostro avere devono rimanere in un rapporto bilanciato. Noi dobbiamo mettere a disposizione un portafoglio abbastanza grande di studi e dobbiamo accrescere nell'opinione pubblica l'accettazione della ricerca clinica. In ultimo, si rende necessario un lavoro di pubbliche relazioni in cui devono essere coinvolti anche altri ambiti della medicina. Idealmente mi immagino che la popolazione svizzera sia talmente informata sulla ricerca clinica, che siano i pazienti stessi a richiedere di partecipare attivamente a uno studio clinico. Pertanto il SAKK si deve presentare all'opinione pubblica come l'organizzazione che si occupa di ricerca sul cancro in modo innovativo e con alto valore clinico e deve essere vista come un servizio ai cittadini. Si rende particolarmente necessaria in questo caso una collaborazione con la Lega svizzera contro il cancro e con le leghe cantonali per la lotta al cancro.

Abbiamo bisogno di uno scambio di opinioni a livello internazionale, e perciò vogliamo motivare e sostenere in particolare i nostri colleghi e colleghe più giovani, affinché compiano soggiorni all'estero di breve durata e partecipino a workshop internazionali.

Il finanziamento della Confederazione è garantito almeno fino alla fine del 2011, ma è necessario eseguire già fin d'ora dei sondaggi al fine di ricevere anche in seguito un sostegno soddisfacente per il nostro lavoro.

Queste sono solo alcune delle tematiche che affronteremo nel 2008. È sempre avvincente lavorare per il SAKK e sono convinto che ne valga la pena.

Istituto Svizzero per la Ricerca Applicata sul Cancro SIAK

Dal cancro agli studi clinici e terapeutici

■ Del Prof. Felix Niggli | Vicepresidente SIAK

Tutti si possono ammalare di cancro: bambini, adulti, uomini e donne. Tuttavia c'è tumore e tumore. Si distinguono centinaia di diverse tipologie di cancro. Il tumore nei bambini è diverso dal tumore negli adulti. Le malattie variano non solo in base all'età, ma anche al sesso. I bambini si ammalano più sovente di leucemia, mentre gli adulti ne sono colpiti di rado, ma sviluppano più sovente un carcinoma (tumore maligno). Le donne si ammalano in genere di tumore al seno, gli uomini di tumore alla prostata. L'incidenza dei tumori sta aumentando nei bambini e in generale negli anziani.

Oggi è chiaro che il tumore è una malattia genetica, quindi si basa su alterazioni di determinati geni dell'organismo umano, che di solito si verificano nel corso della vita. Mentre nei bambini tali geni possono essere modificati in ogni caso già prima della nascita attraverso avvenimenti ancora sconosciuti, le alterazioni negli adulti probabilmente vengono acquisite nel corso del tempo. Le cellule vengono stimolate ad una crescita incontrollata, che in ultimo porta alla formazione di un cancro. Capire e modificare questi meccanismi è un compito importante della ricerca fondamentale nella lotta contro i tumori. L'età, la predisposizione e gli stimoli esterni sono i fattori principali dell'insorgenza di un tumore. Gli obiettivi della ricerca clinica sul cancro sono la lotta al tumore sulla base delle informazioni della ricerca fondamentale o anche la prevenzione attraverso misure adeguate. Perciò al centro di tutto stanno gli studi di ottimizzazione delle terapie, che comprendono le nuove conoscenze della ricerca, per testare l'efficacia dei moderni trattamenti. Gli studi di ottimizzazione delle terapie sono programmi di ricerca medica, in cui vengono esaminate sui pazienti le nuove forme di trattamento (ad es. nuovi farmaci o combinazioni di farmaci e misure terapeutiche). Sono parte di un processo lungo, scrupolosamente pianificato e controllato, allo scopo di rispondere a domande scientifiche e raggiungere un miglioramento dei risultati terapeutici per determinate malattie. Senza tali studi, miglioramenti sostanziali nel trattamento sono a malapena possibili. A ragione va detto che l'oncologia, grazie all'esperienza di anni nella ricerca clinica cooperativa e multi-centrica, è un modello da seguire in altri campi della medicina, in cui viene promossa la ricerca clinica orientata sui pazienti.

Da tempo però non si tratta solo più di migliorare la percentuale di guarigione ma anche la ricerca dei risultati (Outcomes Research), che comprende interrogativi sulla qualità della vita in seguito all'insorgenza del cancro fino all'efficienza dei costi di un certo trattamento, che sta diventando sempre più significativa.

La fine dell'era SIAK

Il SIAK è stato fondato nel 1991 e, insieme ad attività proprie, divenne un'organizzazione mantello per i tre membri: l'Associazione Svizzera Registri Tumori (ASRT), il Gruppo d'Oncologia Pediatrica Svizzera (SPOG) e il Gruppo Svizzero di Ricerca Clinica sul Cancro (SAKK). Insieme al SIAK è stata istituita una piattaforma interdisciplinare valida in tutta la Svizzera per la ricerca clinica sul cancro con un centro di coordinamento che funge da centro direttivo e di servizi. Negli ultimi due anni si è lavorato alla ristrutturazione con l'obiettivo principale di continuare a rafforzare la ricerca clinica sul cancro attraverso la trasparenza e l'efficienza delle strutture e di conferire alle tre organizzazioni dei membri un proprio profilo.

Nella primavera del 2007 è stata istituita la fondazione National Institute for Cancer Epidemiology and Registration (NICER), con l'intento di portare ad un ulteriore rafforzamento dell'epidemiologia tumorale in Svizzera. L'ASRT, che si è staccata dal SIAK, è stata integrata come pilastro portante di questo Istituto. Anche la SPOG, in qualità di associazione indipendente, è uscita dal SIAK, ma rimane strettamente legata al SAKK, in particolare in ambito amministrativo.

In occasione dell'assemblea dei delegati nell'autunno 2007 è stata approvata la fusione del SIAK con il SAKK, il che ha portato, dopo 16 anni, all'integrazione dell'organizzazione precedente SIAK in una partnership/fusione, che in seguito ha proseguito sotto il nome di SAKK. Tutte e due le reti importanti del SIAK, «Outcomes Research» e «Cancer Predisposition Testing and Counseling», sono state integrate nel SAKK. Lo stesso SAKK si è dato una nuova struttura e ha adeguato i suoi statuti di conseguenza. In questo senso, i poteri decisionali degli organi del SAKK sono stati in particolare adattati a criteri moderni ed è stata estesa la base dei membri. In questo processo, tra le altre cose, il Consiglio di Ricerca e il comitato esecutivo sono stati sostituiti con l'assemblea dei membri e con il comitato direttivo.

Ringraziamento alle figure principali del SIAK

Il direttivo del SIAK desidera ringraziare tutti coloro che si sono impegnati negli anni passati per il SIAK e per le relative organizzazioni dei membri nel sostegno della ricerca clinica sul cancro.

Anche se gli obiettivi principali rimangono sostanzialmente gli stessi, i tempi cambiano e richiedono sempre di più degli adeguamenti in base alle mutate condizioni. SAKK, SPOG e NICER continueranno a lavorare per mantenere la ricerca clinica sul cancro ai livelli più alti e per continuarne lo sviluppo.

Gruppo Svizzero di Ricerca Clinica sul Cancro SAKK

Attività del centro di coordinamento

■ Del Dr. Peter Brauchli | Direttore del SAKK

Evoluzione del centro di coordinamento SAKK

Abbiamo continuato a sviluppare in maniera sistematica il nostro compito principale, ovvero l'elaborazione e lo svolgimento di studi clinici qualitativamente superiori nelle indicazioni oncologiche. A tal fine sono state ampliate le capacità e le competenze nei reparti di coordinamento degli studi e di statistica.

La nuova carica di responsabile GCP (Good Clinical Practice) e di Assicurazione qualità è stata assegnata internamente alla sig.ra Doris Lanz. In questo modo è stato possibile coprire in modo più mirato i settori relativi alla redazione e revisione delle Standard Operating Procedures SOP, alla formazione e specializzazione dei medici ricercatori e dei Clinical Research Coordinators CRC nonché all'auditing.

Il centro di coordinamento SAKK può contare ora su una propria segreteria SPOG perché la collaborazione con la SPOG si è consolidata.

La collaborazione con istituzioni esterne e l'assunzione di servizi per terzi ha portato a un aumento del personale. Affinché il centro di coordinamento possa continuare ad adeguarsi alle necessità è necessario prendere in affitto nuovi uffici. In totale il numero di collaboratori stabili del SAKK è cresciuto di cinque persone su 33 (2780 punti percentuale).

I processi dominanti accanto allo sviluppo, alla realizzazione e all'analisi degli studi al centro di coordinamento sono stati lo scioglimento del SIAK e la revisione degli statuti del SAKK. Oltre ai preparativi per la fusione è stato necessario implementare nuovi processi quali ad esempio le procedure all'interno del direttivo e la scelta delle proposte di studio.

Cooperazioni

Oltre alle cooperazioni in atto del SAKK con SENDO (Southern Europe New Drug Organisation) nell'ambito di Studi Fase I e con l'Institut für Statistik und Versicherungsmathematik ISVM di Berna (Istituto di statistica e di matematica assicurativa), ne sono state concordate ed elaborate di nuove.

Il centro di coordinamento del SAKK collabora sempre più con altri fornitori di prestazioni nel settore della ricerca clinica. Mettiamo pertanto le nostre competenze a disposizione di istituti di ricerca accademici in ambito oncologico e per altre indicazioni: e questo per ricambiare anche il sostegno avuto finora dal Segretariato di Stato per la formazione e la ricerca.

I progetti nell'ambito della rete Outcomes Research verranno portati avanti in futuro in cooperazione con lo European Center for Pharmaceutical Medicine (ECPM) di Basilea. In questo senso, con la Dr. Klazien Matter-Walstra possiamo contare ora su una ricercatrice con esperienza nel campo.

Con la Clinical Trial Unit CTU di Berna è stato elaborato un accordo in merito alla formazione di medici titolari di sperimentazioni eCRCs, allo scambio di SOP e allo sviluppo comune di una soluzione banca dati. Il centro di coordinamento collabora in ambito informatico con la Biobank Suisse, una rete virtuale di diverse banche dati sui biomateriali. In seguito si è sviluppata una cooperazione con il Swiss Institute of Bioinformatics (SIB) di Losanna per un progetto sull'analisi dei dati dei marcatori tumorali. La domanda di ammissione del SAKK alla Swiss Clinical Research Network (SCRN) come parte dell'European Clinical Research Infrastructures Network (ECRIN) è in fase di valutazione.

Progetti

Il centro di coordinamento offre anche di servizi per terzi, in particolare nei settori di statistica e coordinamento degli studi. L'obiettivo di questo processo è di offrire sostegno ai medici della rete SAKK, che altrimenti non ne riceverebbero. Questi servizi tornano anche particolarmente utili ai progetti locali. Inoltre è necessario sviluppare nuove competenze nel centro di coordinamento mediante l'acquisizione di progetti esterni al SAKK come ad esempio: studi al di fuori dell'oncologia, la bioinformatica e Outcomes Research.

Come stabilito, entro il 20 giugno 2007 è stato realizzato il sito web del SAKK (www.sakk.ch). Il nuovo sito web si basa sul CMS (Content Management System) e permette agli utenti autorizzati di curare i contenuti del sito. Un obiettivo importante è quello di utilizzare e di potenziare il sito web come fonte di informazioni ma anche come piattaforma di lavoro per gruppi di progetto e per altri organi del SAKK.

La newsletter SAKK di recente istituzione è uscita a intervalli regolari, fornendo informazioni con cadenza trimestrale. Questa comunicazione continuativa è un presupposto indispensabile per creare una rete multimodale come se la immagina il SAKK.

La realizzazione di studi clinici è una parte importante nella formazione dei medici. Nel 2007 si è svolto un corso di due giorni in cui sono stati illustrati i principi di aspetti specifici della realizzazione di studi GCP e SAKK.

Per la prima volta il reparto di statistica ha tenuto un proprio simposio: «Communication between Clinicians and Statisticians: Nasty pitfalls – Great opportunities«. Il simposio ha avuto luogo il 1° Novembre 2007 presso l'Institut für Sozial- und Präventivmedizin ISPMZ (Istituto di medicina sociale e preventiva) dell'Università di Zurigo. L'argomento ha riscosso un grande interesse.

Strategie

Il comitato scientifico (SAKK Advisory Board SAB) si è riunito per la prima volta nel febbraio 2007. Le discussioni e le valutazioni del SAB sono state di importanza per i processi strategici successivi.

Il comitato esecutivo si è riunito a luglio e ha valutato i consigli dell'Advisory Board.

Nel corso della riunione sono state accolte numerose raccomandazioni del SAB, sono state prese le seguenti decisioni e avviati i passi necessari alla loro realizzazione:

- il tumore alla prostata si trasforma in un obiettivo prioritario del SAKK e il gruppo di lavoro sui tumori urogenitali è stato elevato allo stato di gruppo di progetto. Ad esso correlato è il compito di condurre degli studi.
- La sezione di medicina interna riceve l'incarico di elaborare e di presentare almeno un progetto di studio nell'ambito della terapia supportiva o post-terapia.
- I gruppi di progetto devono essere esaminati a intervalli regolari.
- Ai gruppi di progetto devono essere affiancati esperti internazionali.

Nel corso dell'assemblea semestrale di novembre, il comitato esecutivo e i presidenti dei gruppi di progetto hanno discusso di questioni legate agli aspetti organizzativi e strategici.

Le direttive strategiche hanno portato ai relativi dibattiti sull'ulteriore sviluppo dei reparti del centro di coordinamento e sugli obiettivi per il 2008.

Attività di studi

Il SAKK persegue in primo luogo il miglioramento delle terapie tumorali a favore dei pazienti ed è una organizzazione non commerciale.

Accanto agli obiettivi strategici attuali di condurre studi propri per quanto riguarda le indicazioni maggiori e di collaborare con altri gruppi cooperativi per le indicazioni meno frequenti, ci sono anche alcuni nuovi aspetti che hanno determinato la nostra attività di studi.

Per numerose indicazioni, come ad esempio il linfoma follicolare non Hodgkin (NHL) ed il carcinoma dell'esofago operabile (tumore dell'esofago), si è riusciti a portare avanti in maniera sistematica le attività di studi esistenti da anni in queste indicazioni. Per il carcinoma operabile dell'esofago è stato possibile presentare ad un congresso i primi risultati di uno studio iniziato nel 2002. Sulla base di questi risultati e di una ulteriore Fase I/II, è iniziata la pianificazione di uno studio di Fase III. Per l'NHL follicolare il SAKK ha già condotto due studi internazionali Fase III per l'ottimizzazione della terapia con rituximab. È anche previsto un altro studio Fase III.

È stato possibile avviare diversi studi sull'effetto di nuove sostanze. Dato che con il tumore epatocellulare e il linfoma della cellula capsulare vengono esaminate malattie piuttosto rare, anche questi studi vengono condotti con centri in altri paesi europei. Purtroppo nel corso di questa collaborazione è emerso che l'attivazione di studi clinici nell'Ue è molto dispendiosa e legata a molte incertezze.

Con lo studio SAKK 41/06 è stato possibile intraprendere per la prima volta un progetto, che viene condotto in collaborazione con santésuisse e in cui si valuta se è sensata una terapia di mantenimento con bevacizumab in pazienti con cancro colorettale in stadio avanzato dopo la sospensione della chemioterapia.

Per molte forme tumorali si cerca di introdurre una strategia terapeutica adattata al rischio. Al fine di poter trattare i pazienti affetti da NHL in base al proprio fattore di rischio è stato avviato lo studio 38/07, che esamina il valore predittivo di una PET precoce (tomografia per emissione di positroni).

Con lo studio SAKK 95/06 si cerca di capire quale sostegno ottimale è possibile dare ai pazienti nel quadro di un trattamento palliativo.

Membri del consiglio direttivo

- Prof. Richard Herrmann
  Universitätsspital, Basel

- Prof. Daniel Betticher
  Kantonsspital, Freiburg

- Prof. Christoph Renner
  Universitätsspital, Zürich

- Prof. Stephan Bodis
  Kantonsspital, Aarau

- PD Dr. Arnaud Roth
  Hôpital Cantonal Universitaire, Genève

- PD Dr. Yves Chalandon
  Hôpital Universitaire, Genève

- Prof. Beat Thürlimann
  Kantonsspital, St. Gallen

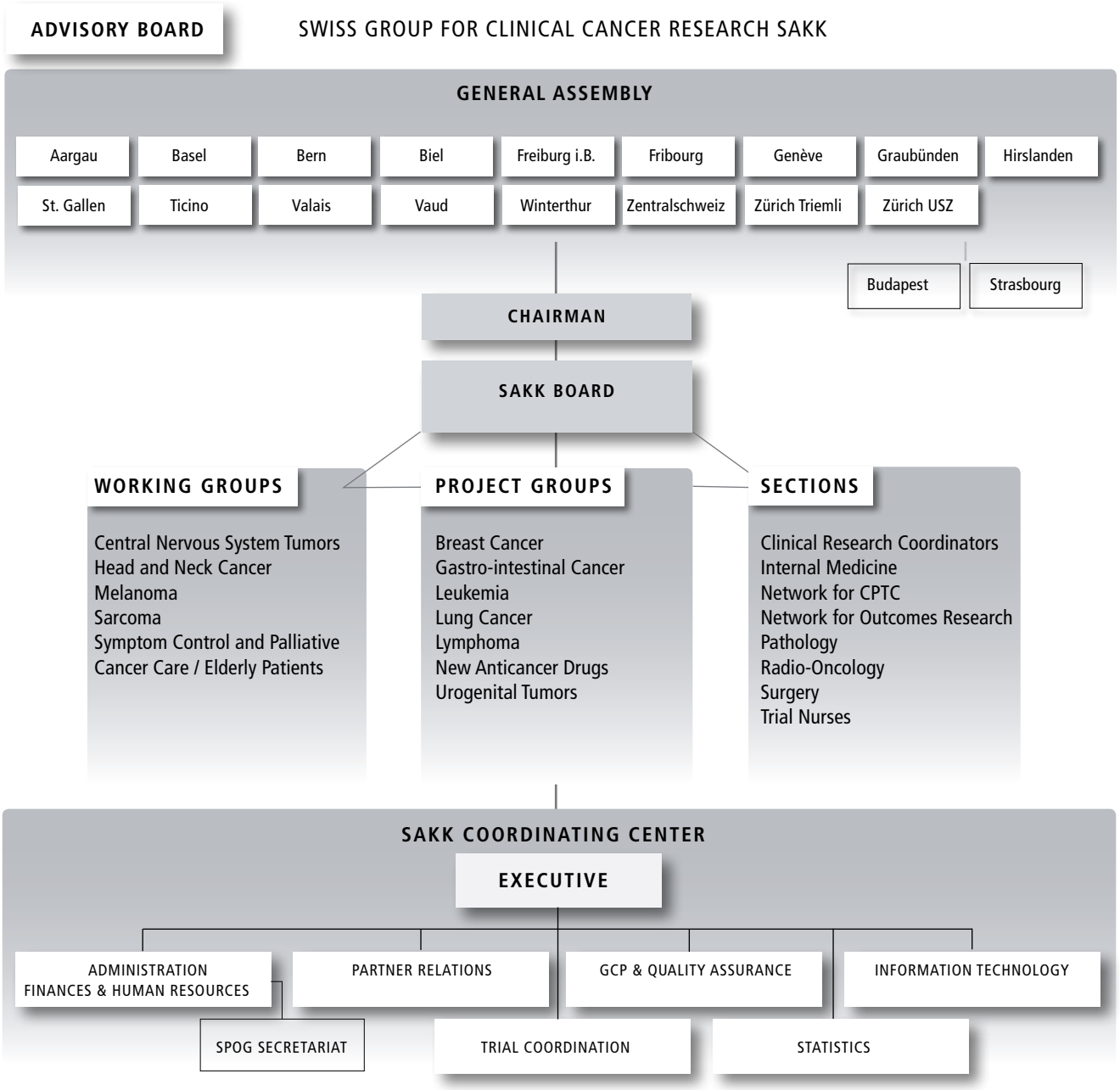
- Prof. Martin Fey
  Inselspital, Bern

- Dr. Roger von Moos
  Kantonsspital, Chur

- Prof. Holger Moch
  Universitätsspital, Zürich

- Prof. Markus Zuber
  Kantonsspital, Olten

Organigramma



Breve profilo

■ Di Chantal Britt I Collaboratrice Partner Relations

Il SAKK è un'organizzazione di pubblica utilità che conduce da più di 40 anni studi nel campo dei tumori in Svizzera. Favorisce, sostiene e coordina progetti di ricerca di medici e altro personale specializzato che sviluppano ulteriormente i trattamenti attuali o che cercano nuove terapie.

Il SAKK vanta un grande grado di notorietà nel settore grazie alla ricerca basata su fondamenti scientifici. Più di 500 medici provenienti dai maggiori ospedali svizzeri hanno preso parte negli ultimi 6 anni a circa 90 studi. Lo scorso anno più di 600 pazienti tra uomini e donne hanno partecipato agli studi coordinati dal SAKK. Il SAKK si è preposto l'obiettivo di rivestire un ruolo sempre più importante anche nell'ambito dei progetti di ricerca internazionali.

Il SAKK coordina e sostiene la collaborazione tra ricercatori, organizzazioni di lotta contro il cancro e istituzioni pubbliche. Rappresenta e diffonde gli interessi di scienziati che svolgono studi sul cancro negli ospedali svizzeri. Pertanto persegue l'obiettivo di migliorare l'efficacia dei trattamenti dei tumori e la qualità della vita dei pazienti. Sostiene l'identificazione delle terapie, che in considerazione di spese e prestazioni aggiuntive hanno effettivamente un vantaggio misurabile per i malati di cancro.

Il SAKK è organizzato come un'associazione che raggruppa come membri i principali centri per la ricerca sul cancro in Svizzera. Il direttivo del SAKK decide sui progetti di ricerca, che vengono elaborati nei gruppi di progetto suddivisi a seconda delle indicazioni. Il centro di coordinamento funge da piattaforma per tutte le prestazioni del SAKK.

Grazie ad una convenzione sulle prestazioni con la Confederazione, il SAKK può svolgere studi clinici in accordo con le direttive accademico-scientifiche e indipendentemente da interessi finanziari. Il SAKK finanzia le sue attività in gran parte con il contributo del Segretariato di Stato per la formazione e la ricerca. Inoltre il SAKK è sostenuto anche dalla Oncosuisse, dalla Ricerca svizzera contro il cancro, dall'industria farmaceutica e da altri finanziatori privati.

Forze dirigenziali, onorificenze e promozioni all'interno del SAKK

Presidente

Prof. Richard Hermann è stato rieletto nel giugno 2007 per il suo secondo mandato in veste di Presidente del SAKK.

Medici dirigenti

- Dr. Dieter Köberle e PD Dr. Silke Gillessen: a partire dal 1° gennaio 2008 dirigenti medici, ospedale cantonale, San Gallo).
- PD Dr. Arnaud Roth: dirigente medico, Oncosurgery Unit, HUG Ginevra.

Docente privato

- Dr. Sergio Cogliatti, Istituto di Patologia, ospedale cantonale,San Gallo

Cattedre

- PD Dr. Christoph Renner, Clinica e Policlinica di Oncologia, Ospedale universitario, Zurigo

Gruppi di progetto SAKK

- PD Dr. Georges Vlastos, HUG Unità Sen. e Oncoginecologia chirurgica, Ginevra: co-presidente del gruppo di progetto sul tumore al seno (succede alla uscente Dr. Olivia Pagani).
- Prof. Walter Weder, Dip. di Chirurgia/Chirurgia Oncologica,ospedale universitario Zurigo: co-presidente del gruppo di progetto sul tumore ai polmoni.
- Prof. Silke Gillessen, Oncologia/Ematologia,ospedale cantonale San Gallo: co-presidentessa del gruppo di progetto sui tumori dell'apparato urogenitale.
- Prof. George Thalmann, primario di clinica e policlinica per l'urologia Anna Seiler-Haus/Inselspital Berna:, co-presidente del gruppo di progetto sui tumori dell'apparato urogenitale.

Presidenti di sezione

- Dr. Sabine Balmer Majno, Div. Radiooncologia HUG Ginevra:,co-presidentessa della sezione di radiooncologia.
- PD Dr. Ludwig Plasswilm, radiooncologia ospedale cantonale San Gallo: co-presidente della sezione radiooncologia.
- Julia Rengier, addetta alla ricerca clinica, Centro Pluridisciplinare di Oncologia CHUV di Losanna: co-presidentessa della sezione Clinical Research Coordinators CRC (succede alla uscente Emmie Okkinga).
- Christine Biaggi Rudolf, centro di coordinamento SAKK di Berna: co-presidentessa della sezione Clinical Research Coordinators CRC (succede alla uscente Emmie Okkinga).

Varie

La sig.ra Anita Margulies, ambulatorio oncologico USZ Zurigo, sezione gruppo specializzato ricerca clinica / Clinical Trial Nurses: comitato esecutivo dell'EONS (European Oncology Society)

Summary of Activities

■ By Dr. Stefanie Lerch and Dr. Ori Schipper I Heads of Trial Coordination SAKK

In 2007, a total of 296 patients were included into 19 SAKK trials (compared to 348 patients in 2006). Additionally, 113 patients were included into IBCSG trials and 168 into trials of foreign groups. This results in a total of 632 patients (729 in 2006) that were included in clinical cancer trials coordinated by SAKK. 8% of the patients (48) included in SAKK trials (88 in 2006) came from foreign centers.

Reasons for the observed decline in accrual are:

- Several trials were closed for accrual during 2006 or in the course of 2007, but no follow-up trials could be implemented.
- Several trials have been closed temporarily for accrual due to interim analysis.

Trials open for accrual in 2007 (activated before 2007)

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). A randomized prospective phase III trial

SAKK 17/04 – Neoadjuvant chemotherapy and extrapleural pneumonectomy of malignant pleural mesothelioma (MPM) with or without hemithoracic radiotherapy. A randomized multicenter phase II trial

SAKK 19/05 – Bevacizumab and erlotinib first-line therapy in advanced non-squamous non-small cell lung cancer (stage IIIB/IV) followed by platinum-based chemotherapy at disease progression. A multicenter phase II trial

Breast Cancer

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 23/03 – Trastuzumab monotherapy followed by the combination of trastuzumab and letrozole in post-menopausal women with ER-positive, HER-2 positive advanced breast cancer resistant to a nonsteroidal aromatase inhibitor. A multicenter two-step phase II trial

SAKK 24/06 – Bevacizumab and pegylated liposomal doxorubicin as first-line therapy for locally recurrent or metastatic breast cancer. A multicenter, single-arm phase II trial

IBCSG TRIAL 22-00 – Low-dose Cytotoxics as «Anti-angiogenesis Treatment» following Adjuvant Induction Chemotherapy for Patients with ER-negative and PgR-negative Breast Cancer

IBCSG TRIAL 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 TRIAL 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 TRIAL 25-02/ BIG 3-02/Tamoxifen and Exemestane Trial (TEXT) – A Phase III Trial Evaluating the Role of Exemestane Plus GnRH Analogue as Adjuvant Therapy for Premenopausal Women with Endocrine Responsive Breast Cancer

IBCSG TRIAL 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 TRIAL 31-03 / IBIS II – International Breast Cancer Intervention Study. A randomised double blind control trial divided into two strata

Leukemia

SAKK 30/00 / HOVON42 – Randomized induction and post induction therapy in adult patients with acute myelocytic leukemia or refractory anemia with excess of blasts (RAEB, RAEB-t) with IPSS score >/= 1.5

CML IV – Randomized Controlled Comparison of Imatinib vs. Imatinib/Interferon – vs. Imatinib 800 mg and Determination of the Role of Allografting in Newly Diagnosed Chronic Phase CML

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

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

CORAL 50-03B – Randomized study of ICE plus rituximab versus DHAP plus rituximab in previously treated patients with CD20 positive diffuse large B-cell lymphoma, eligible for transplantation followed by randomized maintenance treatment with rituximab

HD 13 – Morbus Hodgkin in adults, limited stages

HD 14 – Morbus Hodgkin in adults, intermediate stages

HD 15 – Morbus Hodgkin in adults, advanced stages

IFM 2005-02 – Relevance of maintenance therapy using Lenalidomide (REVLIMID®) after autologous stem cell transplantation in myeloma patients under the age of 65 (Open, randomised, multi-centric trial versus placebo)

Gastro-intestinal Cancer

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 76/02 – Docetaxel and cisplatin chemotherapy followed by radiochemotherapy in patients with inoperable, locally advanced esophageal cancer. A multicenter phase II trial

Sarcoma

EuroEwing 99 – Studie zur Behandlung des Tumors der Ewing-Gruppe

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

Central Nervous System Cancer

SAKK 70/03 – Whole brain radiotherapy in combination with gefitinib (Iressa) or temozolomide (Temodal) for brain metastases from non-small cell lung cancer (NSCLC). A randomized phase II trial

Trials activated in 2007

The following seven SAKK trials were opened for accrual in 2007. In addition, three trials of foreign cooperative groups as well as two IBCSG trials were activated within the SAKK network.

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, multi-centre, open-label, phase III study of adjuvant, lapatinib, trastuzumab their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer

Leukemia

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 81 – Assessment of the tolerability and efficacy of the addition of bevacizumab to standard induction therapy in AML and high risk MDS

Lymphoma

SAKK 36/06 – Everolimus (RAD001) for the treatment of patients with newly diagnosed and 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

IFM 2005-04 = 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

Gastro-intestinal Cancer

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 75/06 – Cetuximab in combination with radiation therapy and chemotherapy prior to surgery in patients with resectable, locally advanced esophageal carcinoma. A multicenter phase Ib-II trial

SAKK 77/06 – Continuous sunitinib treatment in patients with unresectable hepatocellular carcinoma. A multi-center phase II trial

Melanoma

SAKK 50/07 – Temozolomide combined with bevacizumab in metastatic melanoma. A multicenter phase II trial

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

Trials closed in 2007

Breast Cancer

IBCSG TRIAL 26-02/ BIG 4-02/ PERCHE Premenopausal Endocrine Responsive Chemotherapy Trial (PERCHE) – A Phase III Trial Evaluating the Role of Chemotherapy as Adjuvant Therapy for Premenopausal Women with Endocrine Responsive Breast Cancer Who Receive Endocrine Therapy

IBCSG TRIAL 30-06 / MA.27 – A randomized Phase III Trial of Exemestane versus Anastrozole in Postmenopausal Women with Receptor Positive Primary Breast Cancer

IBCSG TRIAL 32-05/ BIG 1-05/ CASA – Chemotherapy Adjuvant Study for women at advanced Age (CASA) Phase III Trial Evaluating the Role of Adjuvant Pegylated Liposomal Doxorubicin (PLD, Caelyx®, Doxil®) for Women (age 66 years or older) with Endocrine Nonresponsive Breast Cancer Who Are NOT Suitable for Being Offered a «Standard Chemotherapy Regimen»

Leukemia

APL 2000 – A randomized trial assessing the role of AraC in combination to ATRA, anthracyclines and maintenance chemotherapy in newly diagnosed acute promyelocytic leukemia (APL)

IFM 2005-01 – Etude multicentrique randomisée de phase III en ouvert comparant l'association Velcade® Dexaméthasone à la chimiothérapie de type VAD pour le traitement des patients porteurs de myélome multiple de novo jusqu'à l'âge de 65 ans

Lymphoma

SAKK 35/03 – Comparing two schedules of rituximab maintenance in rituximab-responding patients with untreated, chemotherapy resistant or relapsed follicular lymphoma

EBMT CLL – The value of autografting younger patients with high risk chronic lymphatic leukemia (CLL). A randomized phase III intergroup trial

Gastro-intestinal Cancer

SAKK 41/03 – Oxaliplatin, irinotecan and capecitabine as a combination regimen for first line treatment of advanced or metastatic colorectal cancer. A multicenter phase I-II trial

Project Group Reports

Breast Cancer Project Group

■ By Dr. Olivia Pagani, MD, Breast Cancer Consultant for the Breast Unit, Oncology Institute of Southern Switzerland, IOSI, Lugano | President (until March 31, 2008)

■ Prof. Stefan Aebi, Associate Professor of Medical Oncology,
University Hospital, Bern | President

■ PD Dr. Georges Vlastos, Department of Gynecology, Breast Unit, University Hospital, Genève | President (starting April 1, 2008)

Objectives of the Project Group

The Breast Cancer Project Group (BCPG) aims to promote and conduct clinical and translational research in breast cancer and to pursue an active collaboration with international research groups, in particular with the International Breast Cancer Study Group (IBCSG). In addition, it provides its members with an opportunity to get updates on the developments in breast cancer research.

Activities and Achievements

The Breast Cancer Project Group held two public and two closed meetings with broad member participation. It is conducting a successful phase II trial of PEG-liposomal doxorubicin in combination with bevacizumab for patients with advanced breast cancer (SAKK 24/06). The group continues to enroll patients in earlier studies, notably into SAKK 22/99 with renewed participation from centers in northern Italy. The group's members play an important role in the activities of the International Breast Cancer Study Group both on a practical level by contributing patients and on an intellectual and leadership level by serving as study chairs.

Projects/Strategies for the Next Years

With the support of SAKK and with the new bylaws and regulations to be developed, the group will strengthen its identity by defining membership criteria intended to promote and facilitate the participation in clinical trials. The Project Group will work with the Board and the SAKK CC to provide a platform for the professional empowerment of younger physician/researchers.

The group will maintain a core activity of cancer drug trials with a preference for investigator-driven studies. For instance, a follow-up trial is being planned for SAKK 24/06. The group will focus on developing non-drug studies (e.g. diagnostic procedures, patient preferences, surgical procedures, economic questions, etc.); to this end a gynecologic surgeon/senologist has been named as one of the co-presidents.

Collaboration with Working Groups, Sections and Other Groups

The group will maintain its traditional affiliation with IBCSG for trials of adjuvant therapy and will try to establish stronger links with the SAKK New Anticancer Drugs Group and other collaborative research organizations such as the European Organisation for Research and Treatment of Cancer (EORTC).

Gastro-intestinal Cancer Project Group

■ By Prof. Markus M. Borner, Head, Clinical Research Unit of the Oncology Department, Inselspital, University of Bern & Head, Oncology Unit, Hospital of Biel I President

Objectives of the Project Group

The logical trial development program for various cancer entities of the GI tract remains a focus of the group. Successful examples are colorectal cancer, gastric cancer or esophageal cancer (see below). The challenge of the near future will be to integrate translational research into clinical treatment protocols. Basically, each treatment protocol, especially if investigating a so-called molecular targeted drug, should ask for tissue sampling for molecular analyses. Such an effort will become a core commitment of SAKK and thus should be orchestrated and organized by centralized efforts in collaboration with Swiss pathologists. The size of Switzerland and its freedom from some restrictive EU laws provide an advantage for internationally competitive clinical research. Colorectal cancer is one of the first cancers where basic molecular understanding will translate into predictive tools (KRAS mutational status for the efficacy of EGFR antibodies). Accordingly, two protocols of the group on differential treatment approaches for rectal cancer according to KRAS mutational status are in preparation. In addition, SAKK is already instrumental in analyzing the large PETACC 3/EORTC 40993/SAKK 60/00 database for molecular markers.

Activities

In esophageal cancer, several papers on different aspects of study 75/02 docetaxel + cisplatin chemo- and radiochemotherapy followed by surgery) have now been submitted. The follow-up protocol 75/06, which is again chaired by Thomas Ruhstaller, includes targeted treatment with cetuximab in the same treatment strategy and is accruing fast. 76/02 is looking at the same chemoradiotherapy combination as 75/02 in inoperable patients and has recently been temporarily closed for accrual. It will be decided in early 2008 whether the accrual can be reopened again. An exciting collaboration with the German group led by Michael Stahl on a randomized study including a molecular targeted molecule is under discussion in the group.

Various proposals are under discussion in metastatic gastric cancer.

Various proposals are under discussion in metastatic pancreatic cancer.

In advanced biliary tract cancer, the results of trial 44/02 (capecitabine + gemcitabine) have now been submitted by Dieter Koeberle. In collaboration with NCI Canada a randomized trial comparing gemcitabine with gemcitabine + capecitabine (SAKK regimen) with strong focus on Quality of Life (QoL) will probably open for accrual in 2008 (local lead Viviane Hess).

In metastatic colorectal cancer, the group has opened its conceptual randomized phase III study 41/06 on the question of maintenance bevacizumab after chemo-immunotherapy under the leadership of Dieter Köberle. Protocol requirements are lean and simple to stimulate rapid accrual. Because of the health economical rationale, the study is supported by santésuisse. Study 41/03 (oxaliplatin + irinotecan + capecitabine) has finally reached its accrual goal for phase I. The phase II part will not be opened.

In the curative neoadjuvant setting of rectal cancer, a protocol by Daniel Helbling is under discussion using a panitumumab combination in KRAS wildtype tumors. In tumors with KRAS mutations, an alternative protocol is planned using an oral multitargeted drug in combination with standard treatment (Roger von Moos and Richard Cathomas).

An innovative protocol on the use of dasatinib in GIST (gastrointestinal stromal tumors) (Michael Montemurro and Serge Leyvraz) will be opened in 2008 (56/07).

Several interesting efforts in hepatocellular carcinoma (HCC) are under way. The study 77/06 of Dieter Koeberle examines the use of sunitinib and shows rapid accrual. Radio-oncologists under the lead of Ilja Ciernik are finalizing an innovative phase I/II protocol on the use of radiotherapy in HCC. Due to the rapid accrual of 77/06, the group is now in the process of exploring new research ideas, possibly in collaboration with Jean-Francois Dufour, who is currently performing a local (Bern) phase I/II protocol combining sorafenib with TACE.

Achievements (for details please refer to SAKK Publications)

Roth et al: 42/99, JCO 2007. For details please refer to «SAKK Publications».

Herrmann et al: 44/00, JCO 2007. For details please refer to «SAKK Publications».

Projects/Strategies for the Next Years & Collaboration with Working Groups, Sections and Other Groups

- Strategical reflections are summarized in the «Objectives of the Project Group».
- Newly established collaboration with the group of Michael Stahl (Germany) for a randomized trial in esophageal cancer.
- The group has institutionalized a close contact to its member Prof. Bodoky in Budapest.
- Close contacts with EORTC and the PETACC group.
- Proposal to participate in a phase III study of the NCI Canada on capecitabine and gemcitabine in advanced biliary tract cancer.
- The group is in close contact with the phase I group of the SAKK (Cristiana Sessa, Piercarlo Saletti) to work on various project proposals.

Leukemia Project Group

■ By PD Dr. Yves Chalandon, Attending Physician, Hematology Service, University Hospital Geneva (HUG) | President

Objectives of the Project Group

The aim of the group is to have active members working in the field of acute and chronic leukemia, offer clinical studies covering the main topics in leukemia, develop phase I-II trials testing new compounds and combinations, intensify translational research, especially in molecular biology, collaborate with international study groups in developing and performing phase III trials, establish a national and international network, be present in international working groups, offer a platform for younger clinical researchers, motivate all Swiss centers in activating their studies.

Activities and Achievements

Activity in clinical phase III trials:

In Acute Myeolid Leukemia (AML)/ high risk myelodysplastic syndromes (MDS): the SAKK 30/00/HOVON 42 is ongoing and testing the value of priming leukemic cells with G-CSF during induction and post-induction chemotherapy in pts ≤60 years. The trial will be closed by mid 2008 and a new phase II-III trial will follow:

The HOVON 92/SAKK 30/08 testing a new alkylating agent VNP40101M (Cloretazine®) in combination with standard AML induction chemotherapy cycle I and II. The phase II will test different doses of Cloretazine® in association with standard chemotherapy in a randomized comparison. Then the feasible dose of Cloretazine® of the phase II will be used in the phase III randomized trial.

The SAKK 30/01/HOVON 43 has been closed in 2006. It was testing the value in a randomized trial, first of increased doses of induction chemotherapy with daunorubicine (anthracycline) and then in a second randomization the value of consolidation with gemtuzumab (anti-CD33) ozogamicin or not in elderly AML/high risk MDS patients (>60 years). The analysis of the results will be done by the end of 2008 – beginning of 2009.

Acute Lymphoblastic Leukemia (ALL): The GRAALL/GRAAPH 2005 has been activated in November 2006 in Switzerland and is already active in France since May 2006, and 309 patients have been included. It is testing the value of intensive versus standard induction and intensification in a randomized comparison and for B-ALL in a second randomization the benefit of rituximab in addition to chemotherapy and for Ph+ ALL in a randomized comparison the non-inferiority of an imatinib based induction

therapy vs. a chemotherapy based induction combined with imatinib.

Acute Promyelotic Leukemia (APL): APL 2000 A randomized trial assessing the roles of AraC and arsenic trioxide (ATO) in newly diagnosed APL. The study has been closed in 2007, and in Switzerland the randomization with ATO or not for patients with > 10'000 white blood cells (WBC) could not be implemented due to non availability of the drug.

APL 2006 will soon be activated and follows the APL 2000 study. This is a randomized trial assessing the role of arsenic trioxide and/or ATRA during consolidation course in newly diagnosed APL.

Chronic Lymphotic Leukemia (CLL): The CLL-7 has been opened in 2007, it is a GCLLSG (German CLL Study Group) randomized trial comparing early treatment with Fludarabine-Cyclophosphamide-Rituximab (FCR) vs. deferred treatment in untreated high risk Binet stage A.

A new trial will be opened in 2008, the CLL-10. It is also a GCLLSG randomized trial that will compare fludarabine, cyclophosphamide, rituximab (FCR), the best standard chemo-immunotherapy at the moment for CLL, with bendamustine-rituximab (BR) in patients with previously untreated CLL. The aim of the study is to investigate the non-inferiority of BR vs. FCR in term of efficacy and to see if there is less toxicities and infection in the study arm.

The CLL/European Group for Blood & Marrow Transplantation EBMT-Trial has been closed without reaching the expected number of patients due to slow accrual. Nevertheless an analysis will be done (the number of patients accrued was close to the one desired). It was testing the value of autografting younger patients with high risk CLL. A randomized phase III intergroup trial.

Chronic Myeloid Leukemia (CML): The CML-IV study with the GCMLSG is ongoing and comparing 3 arms in newly diagnosed CML, imatinib vs. increased doses imatinib, vs. imatinib + IFN. The study will close by mid 2008. A new trial will follow the CML-V, the design of which is not yet finalized, but will compare the best arm of the CML-IV trial with second generation tyrosine kinase inhibitors (TKI) or third generation TKIs in a one-year induction treatment, and then maintenance therapy will depend on the level of response at one year (cytogenetic, molecular).

Multiple Myeloma (MM): The EBMT MMVAR trial has been activated in January 2007 comparing velcade + thalidomide + dexamethasone vs. thalidomide + dexamethasone in MM relapsing after autologous stem cell transplantation.

Activity in Clinical Phase II Trials

CLL: The SAKK 34/02 has been closed in 2006 and was testing the value of 2-CDA and rituximab as remission induction and rituximab as in vivo purging prior to peripheral stem cell mobilization in patients with chronic lymphocytic leukemia. A manuscript is going to be submitted soon.

AML: The HOVON 81 in patients > 60 yrs with AML/high risk MDS has been activated in 2007 and is testing the feasibility and CR rate of adding bevacizumab (anti-VEGF Mab) to induction chemotherapy in a randomized comparison.

Low/intermediate risk MDS: the SAKK 33/99 has been closed in 2006 and was testing the value of ATG + CSA in a phase II study vs. best supportive care.

ALL: The GRAALL 2003 and GRAAPH 2003 were closed in 2006. The GRAAPH 2003 study was published in Blood 2007; 109:1408: Adrienne de Labarthe et al., the GRAALL 2003 study manuscript has just been submitted.

Hairy Cell Leukemia (HCL): The SAKK 32/98 trial has been closed in 2006 and was testing in a randomized study the daily vs. the weekly administration of 2-CDA in patients with HCL.

Translational Research

Cell banking project: the SAKK 63/03 blood and bone marrow banking in SAKK leukemia trials is activated. Now the majority of SAKK centers could activate the study and the hope is that it will finally reach the expected participation in 2008.

Projects/Strategies for the Next Years

- Emphasis on initiation of SAKK phase II trials in elderly patients with acute leukemias (AML, ALL) with new targeted drug therapy (combination, sequential) or vaccines
- Create a Swiss registry database for leukemic patients
- Stimulation of translational research projects (prognostic, MRD as well as study of leukemic stem cells, leukemogenesis, genomic and proteomic, this is already done with collaborative groups, but should be stimulated at the SAKK level)
- Continue the collaboration with international study groups as far as clinical phase III trials are concerned and improve the input of SAKK in those groups as for example being the leader of a phase III trial
- AML: Activation of a SAKK protocol 5-Azacytidine for elderly patients in 2008 to assess the effect of 5-Azacytidine in elderly patients unfit to tolerate induction chemotherapy

- A relapse phase II protocol for AML patients is going to be finalized in 2008
- HCL: A first line protocol is well advanced and should be developed in 2008 testing the value of immunotherapy with rituximab prior to cladribine in randomized comparison.
- CLL: Prepare phase II protocols in pretreated CLL patients
- ALL: Prepare phase II protocols in relapsed ALL and elderly ALL patients

Collaboration with Working Groups, Sections and Other Groups

The Leukemia Project Group (LPG) collaborates with the Lymphoma Project Group within the SAKK and the following other groups:

- The Dutch HOVON group in AML
- The collaborative group GRAALL (Group for Research in Adult Acute Lymphoblastic Leukemia) including the French groups GOELAMS-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 Leukemia Network
- The European Group for Blood and Marrow Transplantation (EBMT)
- Laboratory group (molecular diagnostic), the Swiss Molecular Hematology/Oncology (SMH) working group

Lung Cancer Project Group

■ By PD Dr. Miklos Pless, Head of Medical, Oncology and Tumor Center, Kantonsspital Winterthur | President

■ Prof. Walter Weder, Chairman
Division of Thoracic Surgery
University Hospital Zurich | President

Objectives of the Project Group

The Lung Cancer Project Group is committed to conducting high-quality clinical research projects. It supports the interdisciplinary cooperation in the treatment and research of thoracic tumors. One main focus is the promotion of translational research within the clinical projects. Finally, it helps to advance the career of young clinical researchers.

Activities and Achievements

16/00: This randomized trial, which examines the value of neoadjuvant chemoradiation vs. chemotherapy in stage IIIA Non Small-Cell Lung Cancer (NSCLC) has almost reached its accrual goal (90%). Since all other international trials with the same question have been closed due to poor accrual, the 16/00 trial has become pivotal in trying to define the role of neoadjuvant radiotherapy in this setting. We hope to complete this study in 2008/2009.

16/01: This phase II trial, investigating the value of trimodality therapy in selected stage IIIB NSCLC has finished accrual 2006 and was published as an oral presentation at the world lung cancer meeting in Seoul in 2007. It showed excellent results with a median overall survival of 27 months.

17/04: A randomized phase II study, investigating the role of hemithoracic radiotherapy after neoadjuvant chemotherapy and surgery in mesothelioma, is accruing well. One problem is the relatively low number of patients randomized after induction chemotherapy and surgery, partly due to R1/2 resection, partly due to refusal of patients. In 2008 the first planned interim analysis will determine whether to continue with the randomized trial, or to switch to a single arm modus.

19/05: A phase II trial in first line (non-squamous) NSCLC with a combination of bevacizumab and erlotinib. The amendment to make fresh tissue sampling compulsory has been implemented. Since then the accrual has been

slightly slower. The study was also closed temporarily for the second efficacy analysis, but will be reopened early in 2008. 23 additional patients have to be included.

Projects/Strategies for the Next Years

Projects: In adjuvant NSCLC we plan to join the Eastern Cooperative Oncology Group (ECOG) study investigating the effect of adjuvant bevacizumab, negotiations are under way. For stage IIIA we are waiting for the 16/00 trial to complete accrual before developing a new protocol, several (cooperative) groups have expressed interest to work with us (EORTC, Erlangen, Belgian and Dutch lung cancer group). In stage IIIB a project was drafted last year using sorafinib and radiotherapy, but due to the unexpected high toxicity of sorafinib together with radiation in other pilot studies, this project was dropped. A new protocol is being written. In stage IV NSCLC several follow-up projects of the 19/05 trial are being pursued. One is to join the Spanish group in EGFR mutated patients, evaluating erlotinib vs. chemotherapy in first line NSCLC treatment. In SCLC we were unable to get an interesting new drug for evaluation so far (mTOR or other), we are still working on that project.

Strategies: We will keep focusing on stage III NSCLC and Mesothelioma. The bio-bank project is advancing well and we will continue to do trials with experimental drugs in first-line treatment of stage IV NSCLC, with the opportunity to define biomarkers in blood, tissue and by cDNA arrays.

Collaborations with Working Groups, Sections and Other Groups:

- Planned: ECOG: Bevacizumab in adjuvant NSCLC
- Planned: Spanish lung cancer group in stage IV NSCLC with EGFR mutation.

Lymphoma Project Group

■ By PD Dr. Nicolas Ketterer, Attending Physician, Centre Pluridisciplinaire d'Oncologie, Lausanne | President

Objectives of the Project Group

The Lymphoma Project Group's main objectives are to conduct innovative and valuable clinical research in onco-hematology, to activate and lead innovative trials, but also to participate in important international projects and collaborative studies. The group gets together people interested in this field and provides opportunities for young investigators to develop research in lymphoma or myeloma.

Activities and Achievements

Regarding certain aspects, last year may be considered as a pivotal year, insofar as some major trials were closed (35/03, IFM 05-01), but yet were not replaced by new generation trials. At the same time, very important new trials were activated.

In **follicular lymphoma**, the SAKK 35/03 trial (short versus prolonged rituximab maintenance) closed in September 2007, confirming the presence of our group in this field and its ability to successfully lead a critical international trial.

In **diffuse large B cell lymphoma**, the SAKK 38/07 trial (prospective evaluation of PET in patients treated with R-CHOP14) was activated in October 2007. For patients in first relapse, the CORAL study is still open and a first interim analysis was presented at the ASH meeting in December. Our Group's contribution is significant with 21 patients included in Switzerland. For elderly patients in relapse (SAKK 37/05), the 1st dose-level of melphalan/Zevalin was completed.

SAKK 36/06 trial testing everolimus in patients with mantle cell lymphoma was activated last summer, and represents a very challenging trial with international collaboration.

In **Hodgkin lymphoma**, the final results of the HD 7 and HD 8 trials were published in 2007 in the JCO and in the Annals of Oncology, respectively. The HD 13, 14 and 15 trials continued to accrue very well last year in Switzerland.

Concerning **multiple myeloma**, the IFM 2005-01 trial closed early in 2007. Unfortunately, regulatory issues and a very rapid accrual in France prevented our group from including more than 13 patients. The post-autologous stem-cell transplantation (ASCT) maintenance 2005-02

trial started to recruit in 2007. It may include patients who were not treated in the 2005-01 protocol. Another collaborative myeloma study (EBMT MMVAR trial) was activated in May 2007 and compares Thal/Dex to Velcade/Thal/Dex in patients relapsing after ASCT. Two papers were published last year and acknowledged the SAKK contribution. One analyzes survival according to genetic abnormalities (Avet-Loiseau H, Blood), and the other reports on patients with t(4;14) treated in the IFM99 trial (Moreau P, Leukemia).

Projects/Strategies for the Next Years and Collaboration with Working Groups, Sections and Other Groups

Considering the international competition, our Project Group cannot be the leader in every field of onco-hematology, but has to develop a few key studies. The most important challenge in 2008 is to start the new SAKK 35/08 trial for untreated follicular lymphoma. This will be a very important and ambitious intergroup trial led by the SAKK, with the collaboration of the Nordic group and other foreign countries.

Our second focus this year will be to develop a trial for elderly patients with diffuse large B cell lymphoma. There is a continuous increase in the number of elderly patients diagnosed each year with DLBCL, and the management of these remains frequently a difficult issue. A group of young investigators started to work on a project, knowing that very few protocols exist in other countries.

Strategies for the next years will also be for the group to work on translational research and to develop a project that could be led together with the New Drugs/Phase I Project Group.

In parallel to these main areas of research, our group must continue to have international visibility through active cooperation with other collaborative groups like the GHSG (German Hodgkin Study Group), GELA (Groupe d'Etude des Lymphomes de l'Adulte), IFM (Intergroupe Francophone du Myélome), and EBMT (European Group for Blood and Marrow Transplantation).

New Anticancer Drugs / Phase I Trials

■ By PD Dr. Cristiana Sessa, Vice-Head Oncology Institute of Southern Switzerland (IOSI) I President

Objectives of the Project Group

The primary aim of the group is to increase the active participation of selected centers to Phase I trials so that the same drugs could be proposed for Phase II trials within SAKK; the group also aims to increase its experience in early drug development and set up a central coordination in this field. The group also aims to strengthen its collaboration with SENDO (Southern Europe New Drugs Organization).

Activities and Achievements

During the second year of activity four institutions (IOSI, Bellinzona; KSSG, St. Gallen; CePO, CHUV, Lausanne; KSS, Basel) were full members while the Department of Medical Oncology, Kantonsspital, Chur started its participation as probationary member by activating a Phase I trial.

The group held two general meetings during the SAKK semi-annual meetings, each with a public session open to all interested parties with one drug company presenting its pipeline and the compounds of interest for the group (Novartis in Bern and Eli Lilly in Basel). Two interim meetings took place in May and October 2007.

A joint evaluation among the involved parties after two years of collaboration of SAKK and SENDO was held in November 2007 before the SAKK semi-annual meeting. Overall, the evaluation was positive, and it was agreed to continue the collaboration; aspects to be improved (mainly the process of planning and implementation of new trials, monitoring, budgeting of trials and collaboration with sites) were pointed out and proposals for changes were defined.

The Investigator Supported Studies (ISS) logistics and system proposed by SENDO Foundation was presented during the SAKK semi-annual meeting in June and was partly implemented in the two Phase IB trials activated in 2007.

The SAKK SENDO Association was legally recognized in December 2007.

Trials

The Phase I trial with the oral platinum compound satraplatin in combination with capecitabine was completed; 36 patients overall (24 in 2007) were accrued in four centers over a period of 18 months, therefore with only three months delay over the expected date of closure (July 2007). An abstract on behalf of SAKK SENDO has been submitted to ASCO.

The Phase I trial with the FAS ligand APO010, a recombinant heptameric peptide developed by Apoxis, now Topotarget (Copenhagen) has accrued 20 patients by December 2007. No dose-limiting toxicities (DLT) had been encountered at the highest dose level foreseen in the protocol and an amendment with three additional dose levels has been prepared and submitted.

The dose finding trial with the dual EGFR VEGFR inhibitor ZD6474 (Zactima) and gemcitabine in previously untreated patients with advanced pancreatic cancer had defined the recommended dose (RD); the dose finding evaluation of the three-drug combination with ZD6474, gemcitabine and capecitabine has been implemented as amendment of the trial.

The first in humans (FIH) Phase I trial of the new campthotecin analogue ST1968 by SigmaTau was started in Bellinzona and St. Gallen, and 11 patients were accrued by December 2007.

Two new phase IB studies were prepared and implemented in 2007 and will be activated in 2008: The combination of satraplatin and oral navelbine in patients with advanced solid tumors (Bellinzona and Chur) and, respectively, the combination of the oral histone deacetylase inhibitor Panobinostat (LBH 589) with paclitaxel and carboplatin (Bellinzona, Lausanne, Basel), the latter with a pharmacodynamic component with serial assessments of the histone and tubulin acetylation levels in peripheral blood mononuclear cells (PBMC) during the first cycle.

Achievements

Plans for 2008 had to be modified due to the Oncology Drugs Advisory Committee's (ODAC) negative evaluation of the randomized Phase III trial satraplatin versus best supportive care in advanced prostate cancer, that brought about a drastic decrease of the planned clinical development with cancellation of phase II projects, and the still ongoing discussion within the GI group of future Phase II studies in advanced pancreatic cancer.

The ISS system proposed by SENDO Foundation was partly implemented in the two Phase IB trials set up in 2007.

Projects

Two major objectives were set for clinical trials, the acquisition of new innovative molecules (at least one with molecular target) for Phase I trials (at least one with translational evaluation) and the introduction of new molecules for Phase II evaluation within the SAKK.

From an administrative and logistics point of view, the improvement of budgeting, implementation and monitoring of SAKK SENDO studies in collaboration with SAKK are the main objectives for 2008.

Strategies for the Next Years

Some of the strategies defined for 2007 are confirmed (activation of Phase II trials, acquisition of new compounds for Phase I), the new implemented system for ISS is to be verified in the two Phase IB trials recently started, the ongoing collaboration between the involved parties in SAKK SENDO is to be further improved.

Urogenital Tumors Project Group

■ By PD Dr. Silke Gillessen, Medical Oncology, Kantonsspital St. Gallen | President

■ Prof. George Thalmann, Department of Urology, Inselspital Bern | President

Objectives of the Project Group

This group was only upgraded from a Working Group to a Project Group in September 2007. The main objectives of the group are: to emphasize the importance of prostate cancer as a research topic in Switzerland and at SAKK; to conduct clinical trials, ideally associated with translational research mainly in patients with prostate cancer, but also with other types of urogenital cancer. In addition, the group should provide an interdisciplinary forum for discussions with colleagues from other specialties that will allow the initiation of collaborative research proposals in urogenital cancer.

A further aim of the group is to strengthen the bonds between the different academic and non academic clinics/hospitals in Switzerland to ensure inclusion of patients in joint trials, but also in clinical trials only available at certain centers.

Activities and Achievements in 2007

The Urogenital Tumors Project Group held two public and two closed meetings to outline the direction and strategies in research to be taken and started a task force for the interdisciplinary development of guidelines for the follow-up of patients with testicular cancer. This task force met three times in 2007.

New Clinical Trials

The SAKK protocol 08/07 was developed. This protocol investigates the safety and efficacy of cetuximab in combination with docetaxel as second-line treatment in patients with hormone-refractory prostate cancer resistant to docetaxel therapy.

Swiss guidelines for the follow-up for patients with testicular cancer were formulated by a task force with members of the group including urologists, radio-oncologists and oncologists.

Ongoing Clinical Trials

Currently there are no ongoing trials.

Projects/Strategies for the Next Years

After years of low participation of members, due to the fact that the Urogenital Tumors Project Group was a working group for many years now, the group first has to be built up again and a network established anew. The strategy of the group is to increase and enforce collaboration between the different disciplines, mainly urologists, oncologists and radio-oncologists, but also pathologists and basic researchers to strengthen the translational research aspects from the beginning of the development of a new clinical protocol.

Younger members will be encouraged to develop new ideas and supported in planning and writing of protocols for clinical trials. This involvement of younger colleagues should allow us to grow a strong network for the future.

The group will build up a core activity of cancer drug trials with a preference for investigator-driven studies. A strong focus will be on newer molecules, especially targeted therapies for patients with prostate cancer as this is a special population of older patients and often with serious co-morbidities.

Collaboration with Working Groups, Sections and Other Groups

The collaboration with the New Anticancer Drugs / Phase I trials Group will be enforced to facilitate the fast development of trials using interesting new drugs in different urogenital cancers. As novel therapeutic approaches are necessary, namely in prostate cancer but also in other types of urogenital cancer, the group will focus on new compounds.

Furthermore, efforts to collaborate on an international level are ongoing. The group is in contact with the Medical Research Council of the UK to participate in a clinical trial on primary treatment of locally advanced and metastatic hormone dependent prostate cancer.

Networks

Network for Cancer Predisposition Testing and Counseling

■ By PD Dr. Pierre O. Chappuis, and Prof. André-Pascal Sappino | Presidents of the Network

Summary of Activities

In accordance with the law regulating predictive genetic testing in Switzerland (cf. KLV/OPAS/OPre art. 12, let. v and the new Law on Human Genetic Analysis, April 1, 2007), 19 centers located in 11 cities throughout Switzerland provide appropriate genetic counseling and evaluation for cancer predisposition testing. More than 400 new families have been managed this year. Up to December 2006, 520 complete screenings of the BRCA1/BRCA2 genes have been completed in 505 distinct families in the Swiss reference molecular laboratory located in Geneva. Pathogenic mutations have been identified in 18.5% of these families and unclassified variants were characterized in 14.5% of index cases tested. We initiated a research project to describe the characteristics of all these breast/ovarian cancer families with screening of BRCA1/BRCA2 germ-line mutations. The national reference laboratory for BRCA1/BRCA2 screening (Laboratory of Molecular Oncology, HUG, Geneva) was associated with 2 other European laboratories of molecular genetics (Leuven and Leiden Universities) to validate a promising new method, the high-resolution melting curve analysis, for the screening of BRCA1/BRCA2 alterations. The draft of the Swiss referral guidelines for genetic counseling and evaluation for BRCA1/BRCA2 testing has been approved by the Swiss Society for Medical Oncology, the Swiss Society of Medical Genetics and the Swiss Society for Senology. The final approval by the Swiss Society of Gynecology & Obstetrics is pending. These guidelines have been prepared for the clinicians to help them identify situations where a syndrome of hereditary breast/ovarian cancer should be suspected, and an adequate management could be proposed.

The two IBIS II breast cancer prevention trials are open in some centers in Switzerland. In 2007, eight women have been included in St. Gallen, Bern, Ticino, and Geneva. The IBIS II-Prevention trial is designed to evaluate anastrozole vs. placebo as an effective method of preventing breast cancer in postmenopausal women at increased risk of the disease. The IBIS II-DCIS trial compares anastrozole vs. tamoxifen as an effective breast cancer preventive drug for postmenopausal women with conservatively-treated ductal in situ cancer. The Network for CPTC has joined the Orphanet database as a professional network, as well as some oncogenetic counseling centers in Switzerland (cf. www.orpha.net).

Network for Outcomes Research

■ By Dr. Klazien Matter-Walstra, European Center for Pharmaceutical Medicine, Basel | Senior research scientist

Summary of Activities

Since November 2007 Dr. Klazien Matter-Walstra has taken up the newly created position of a senior researcher in outcomes research, located at the European Center of Pharmaceutical Medicine (ECPM). Dr. Matter-Walstra will work in close cooperation with the SAKK on outcomes and health economics research in ongoing and upcoming clinical trials. Research projects on the basis of observational, retrospective or published data are also envisaged.

Initial activities focus on the assessment of the current status of ongoing projects and on those SAKK protocols which require immediate outcomes research-related or health economic activity (e.g., SAKK trials 16/00, 35/03, 35/08).

Primary tasks include(d) acquiring an overview of existing materials concerning health economic data for the above-mentioned trials, assigning priorities and defining health economic research designs. In close collaboration with the trial chairpersons, study coordinators and various data providers, data collecting and processing procedures are now initiated in a pilot phase for the studies SAKK 16/00 and SAKK 35/03. Contacts to several health insurance companies and health care providers such as treating hospitals have been established and first patient data from these data providers are currently being evaluated.

As a secondary task, the feasibility and necessity of retrospective health economic analyses of nearly closed or closed trials will be assessed in the near future. For newly initiated trials, in which health economic or other outcomes research activities are planned or required, a close and early cooperation with all involved parties will be sought.

In order to coordinate and bring together the members of the Network Outcomes Research and other interested researchers, a first network meeting has been scheduled for March 26, 2008.

Dr. Matter-Walstra is primarily based at the ECPM office in Basel but is also present on a regular basis at the SAKK Coordinating Center in Bern.

Publications 2007

SAKK and Collaborating Groups

■ By Dr. Shu-Fang Hsu Schmitz | Head of Statistics
and Dr. Peter Brauchli | Director SAKK

Impact Factors

SAKK trials (9 publications) obtained a total of 58.8 Impact Factor points (based on Impact Factor 2006). IBCSG trials (9 publications) obtained 121.5 Impact Factor points. The participation in further international trials (11 publications) resulted in 105.6 Impact Factor points.

Urogenital Cancer

SAKK 08/91-08/00

Münger-Beyeler C, Bernhard J, Rufibach K, Morant R, Schmid HP. Quality of analgesic treatment in patients with advanced prostate cancer: do we do a better job now? The Swiss Group for Clinical Cancer Research (SAKK) experience. Support Care Cancer. 2007 Oct 2: 17909864. [Epub ahead of print]. (Journal impact factor 1.905)

EORTC trial 22911

van der Kwast TH, Collette L, Van Poppel H, Van Cangh P, Vekemans K, DaPozzo L, Bosset JF, Kurth KH, Schröder FH, Bolla M for the EORTC Radiation Oncology and Genito-Urinary Tract Cancer Groups. Identification of patients with prostate cancer who benefit from immediate postoperative radiotherapy (EORTC trial 22911). J Clin Oncol 25 (27): 4178-86, 2007. (Journal impact factor 13.598)

Lung Cancer

SAKK 17/00

Weder W, Stahel RA, Bernhard J, Bodis S, Vogt P, Ballabeni P, Lardinois D, Betticher D, Schmid R, Stupp R, Ris HB, Jermann M, Mingrone W, Roth AD, Spiliopoulos A for the Swiss Group for Clinical Cancer Research. Multicenter trial of neoadjuvant chemotherapy followed by extrapleural pneumonectomy in malignant pleural mesothelioma. Annals of Oncology 18: 1196-1202, 2007. (Journal impact factor 5.179)

SAKK 19/03

D'Addario G, Rauch D, Stupp R, Pless M, Stahel R, Mach N, Jost L, Widmer L, Tapia C, Bihl M, Mayer M, Ribi K, Lerch S, Bubendorf L, Betticher DC. Multicenter phase II trial of gefitinib first-line therapy followed by chemotherapy in advanced non-small-cell lung cancer (NSCLC): SAKK protocol 19/03. Ann Oncol. 2007 Dec 19; [Epub ahead of print] PMID: 18096565 [PubMed – as supplied by publisher] (Journal impact factor 5.179)

Breast Cancer

SAKK 21/00

Perey L, Paridaens R, Hawle H, Zaman K, Nolé F, Wildiers H, Fiche M, Dietrich D, Clément P, Köberle D, Goldhirsch A, Thürlimann B. Clinical benefit of fulvestrant in postmenopausal women with advanced breast cancer and primary or acquired resistance to aromatase inhibitors: final results of phase II Swiss Group for Clinical Cancer Research Trial. Annals of Oncology 18: 64-69, 2007. (Journal impact factor 5.179)

SAKK 26/00

Gick U, Rochlitz C, Mingrone W, Pestalozzi B, Rauch D, Ballabeni P, Lanz D, Hess V, Aebi S. Efficacy and Tolerability of Capecitabine with Weekly Paclitaxel for Patients with Metastatic Breast Cancer: A Phase II Report of the SAKK. Oncology 5; 71(1-2): 54-60, 2007. (Journal impact factor 2.252)

IBCSG Trial 12 and 14

Colleoni M, Gelber S, Simoncini E, Pagani O, Gelber RD, Price KN, Castiglione-Gertsch M, Coates AS, and Goldhirsch A. 2007. Effects of a treatment gap during adjuvant chemotherapy in node-positive breast cancer: results of International Breast Cancer Study Group (IBCSG) Trials 13-93 and 14-93. Ann Oncol 18:1177-1184. (Journal impact factor 5.179)

IBCSG Trial 16-98

Coombes RC, et al.; Intergroup Exemestane Study. Survival and safety of exemestane versus tamoxifen after 2-3 years' tamoxifen treatment (Intergroup Exemestane Study): a randomised controlled trial. Lancet 369:559-570, 2007. (Journal impact factor 25.8)

IBCSG Trial 18-98

Coates AS, et al. Five years of letrozole compared with tamoxifen as initial adjuvant therapy for postmenopausal women with endocrine-responsive early breast cancer: update of study BIG 1-98. J Clin Oncol 25: 486-492, 2007. (Journal impact factor 13.598)

Keshaviah A, Dellapasqua S, Rotmensz N, Lindtner J, Crivellari D, Collins J, Colleoni M, Thurlimann B, Mendiola C, Aebi S, et al. 2007. CA15-3 and alkaline phosphatase as predictors for breast cancer recurrence: a combined analysis of seven International Breast Cancer Study Group trials. Ann Oncol 18:701-708. (Journal impact factor 5.179)

Mouridsen H, Keshaviah A, Coates AS, Rabaglio M, Castiglione-Gertsch M, Sun Z, Thurlimann B, Mauriac L, Forbes JF, Paridaens R, et al. 2007. Cardiovascular adverse events during adjuvant endocrine therapy for early breast cancer using letrozole or tamoxifen: safety analysis of BIG 1-98 trial. J Clin Oncol 25:5715-5722. (Journal impact factor 13.598)

Viale G, Regan MM, Maiorano E, Mastropasqua MG, Dell'Orto P, Rasmussen BB, Raffoul J, Neven P, Orosz Z, Braye S, et al. 2007. Prognostic and predictive value of centrally reviewed expression of estrogen and progesterone receptors in a randomized trial comparing letrozole and tamoxifen adjuvant therapy for postmenopausal early breast cancer: BIG 1-98. J Clin Oncol 25:3846-3852. (Journal impact factor 13.598)

Mauriac L, Keshaviah A, Debled M, Mouridsen H, Forbes JF, Thurlimann B, Paridaens R, Monnier A, Lang I, Wardley A, et al. 2007. Predictors of early relapse in postmenopausal women with hormone receptor-positive breast cancer in the BIG 1-98 trial. Ann Oncol 18:859-867. (Journal impact factor 5.179)

IBCSG Trial VIII

Bernhard J, Zahrieh D, Castiglione-Gertsch M, Hürny C, Gelber RD, Forbes JF, Murray E, Collins J, Aebi S, Thürlimann B, Price KN, Goldhirsch A, Coates AS, for the IBCSG. Adjuvant chemotherapy followed by goserelin compared with either modality alone: the impact on amenorrhea, hot flashes, and quality of life in premenopausal patients – the International Breast Cancer Study Group Trial VIII. J Clin Oncol 25:263-270, 2007. (Journal impact factor 13.598)

IBIS-I trial

Cuzick J, Forbes JF, Sestak I, Cawthorn S, Hamed H, Holli K, Howell A; International Breast Cancer Intervention Study I Investigators. Long-term results of tamoxifen prophylaxis for breast cancer-96-month follow-up of the randomized IBIS-I trial. J Natl Cancer Inst. 2007 Feb 21;99(4):272-82. (Journal impact factor 15.271)

IBCSG Trial 28-02

Smith I, Procter M, Gelber RD, Guillaume S, Feyereislova A, Dowsett M, A. Goldhirsch A, Untch M, Mariani G, Baselga, Kaufmann JM, Cameron D, Bell R, Berg J, Coleman R, Wardley A, N. Harbeck, Lopez RI, Mallmann P, Gelmon K, Wilcken N, Wist E, Sanchez Rovira P, Piccart-Gebhardt MJ, for the HERA study team. 2-year follow-up of trastuzumab after adjuvant chemotherapy in HER2-positive breast cancer: A randomized controlled trial. Lancet 369 (9555): 29-36, 2007. (Journal impact factor 25.8)

EORTC 10994/BIG 00-01 substudy

Bonnefoi H, Potti A, Delorenzi M, Mauriac L, Campone M, Tubiana-Hulin M, Petit T, Rouanet P, Jassem J, Blot E, Becette V, Farmer P, André S, Acharya CR, Mukherjee S, Cameron D, Bergh J, Nevins JR, Iggo RD. Validation of gene signatures that predict the response of breast cancer to neoadjuvant chemotherapy: a substudy of the EORTC 10994/BIG 00-01 clinical trial. Lancet Oncol 8 (12): 1071-1078, 2007. (Journal impact factor 10.119)

Leukemia

SAKK 37/95

Laurencet F, Ballabeni P, Rufener B, Hess U, Cerny T, Fey M, Luthi J-M, Plancherel C, Zulian G B for the Swiss Group for Clinical Research (SAKK). The Multicenter Trial SAKK 37/95 of Cladribine, Cyclophosphamide and Prednisone in the Treatment of Chronic Lymphocytic Leukemias and Low-Grade Non-Hodgkin's Lymphomas. Acta Haematol 2007;117:40–47. (Journal impact factor 1.564)

HOVON-SAKK

Cornelissen JJ, van Putten WL, Verdonck LF, Theobald M, Jacky E, Daenen SM, van Marwijk Kooy M, Wijermans, P, Schouten H, Huijgens PC, van der Lelie H, Fey M, Ferrant A, Maertens J, Gratwohl A, Lowenberg B. Results of a HOVON/SAKK donor versus no-donor analysis of myeloablative HLA identical sibling stem cell transplantation in first remission acute myeloid leukemia in young and middle-aged adults: benefits for whom? Blood. 2007 May 1;109(9):3658-66. (Journal impact factor 10.37)

LALA-94 Trial

Tavernier E, Boiron JM, Huguet F, Bradstock K, Vey N, Kovacsovics T, Delannoy A, Fegueux N, Fenaux P, Stamatoullas A, Tournilhac O, Buzyn A, Reman O, Charrin C, Boucheix C, Gabert J, Lhéritier V, Vernant JP, Dombret H, Thomas X; GET-LALA Group; Swiss Group for Clinical Cancer Research SAKK; Australasian Leukaemia and Lymphoma Group. Outcome of treatment after first relapse in adults with acute lymphoblastic leukemia initially treated by the LALA-94 trial. Leukemia. 2007 Sep; 21(9):1907-14. (Journal impact factor 6.146)

GRAAPH-2003

Labarthe de A, Rousselo Ph, Huguet-Rigal F, Delabesse E, Witz F, Maury S, Réa D, Cayuela J-M, Vekemans M-C, Reman O, Buzyn A, Pigneux A, Escoffre M, Chalandon Y, MacIntyre E, Lhéritier V, Vernan J-P, Thomas X, Ifrah N, and Dombre H for the Group for Research on Adult Acute Lymphoblastic Leukemia (GRAALL). Imatinib combined to induction or consolidation chemotherapy in younger patients with de novo Philadelphia chromosome-positive acute lymphoblastic leukemia. Blood. 2007 Feb 15;109(4):1408-13. (Journal impact factor 10.37)

CML

Hehlmann R, Berger U, Pfirrmann M, Heimpel H, Hochhaus A, Hasford J, Kolb H J, Lahaye T, Maywald O, Reiter A, Hossfeld, D K, Huber C, Löffler H, Pralle H, Queisser W, Tobler A, Nerl C, Solenthaler M, Goebeler ME, Griesshammer M, Fischer T, Kremers S, Eimermacher H, Pfreundschuh M, Hirschmann WD, Lechner K, Wassmann B, Falge C, Kirchner HH, Gratwohl A, the SAKK and the German CML-Study Group. Drug Treatment is Superior to Allografting as First Line Therapy in Chronic Myeloid Leukemia. Blood. 2007 Jun 1;109(11):4686-92. (Journal impact factor 10.37)

Lymphoma

IFM

Avet-Loiseau H, Attal M, Moreau P, Charbonnel C, Garban F, Hulin C, Leyvraz S, Michallet M, Yakoub-Agha I, Garderet L, Marit G, Michaux L, Voillat L, Renaud M, Grosbois B, Guillerm G, Benboubker L, Monconduit M, Thieblemont C, Casassus P, Caillot D, Stoppa A-M, Sotto J-J, Wetterwald M,

Dumontet C, Fuzibet J-G, Azais I, Dorvaux V, Zandecki M, Bataille R, Minvielle S, Harousseau J-L, Facon T, and Claire Mathiot C. Genetic abnormalities and survival in multiple myeloma: the experience of the Intergroupe Francophone du Myélome. Blood. 2007 Apr 15;109(8):3489-95. (Journal impact factor 10.37)

IFM 99 Trials

Moreau P, Attal M, Garban F, Hulin C, Facon T, Marit G, Michallet M, Doyen C, Leyvraz S, Mohty M, Wetterwald M, Mathiot C, Caillot D, Berthou C, Benboubker L, Garderet L, Chaleteix C, Traullé C, Fuzibet JG, Jaubert J, Lamy T, Casassus P, Dib M, Kolb B, Dorvaux V, Grosbois B, Yakoub-Agha I, Harousseau JL, Avet-Loiseau H. Heterogeneity of t(4;14) in multiple myeloma. Long-term follow-up of 100 cases treated with tandem transplantation in IFM99 trials. Leukemia. 2007 Sep;21(9):2020-4. (Journal impact factor 6.146)

HD7

Engert A, Franklin J, Eich HT, Brillant C, Sehlen S, Cartoni C, Herrmann R, Pfreundschuh M, Sieber M, Tesch H, Franke A, Koch P, de Wit M, Paulus U, Hasenclever D, Loeffler M, Müller RP, Müller-Hermelink HK, Dühmke E, Diehl V. Two cycles of doxorubicin, bleomycin, vinblastine, and dacarbazine plus extended-field radiotherapy is superior to radiotherapy alone in early favorable Hodgkin's lymphoma: final results of the GHSG HD7 trial. J Clin Oncol. 2007 Aug 10;25(23):3495-502. (Journal impact factor 13.598)

HD8

Klimm B, Eich H, Haverkamp H, Lohri A, Koch P, Boissevain F, Trenn G, Worst P, Duhmke E, Muller R, Muller-Hermelink K, Pfistner B, Diehl V, Engert A. Poorer outcome of elderly patients treated with extended-field radiotherapy compared with involved-field radiotherapy after chemotherapy for Hodgkin's lymphoma: an analysis from the German Hodgkin Study Group. Annals of Oncology. 18(2):357-63, 2007. (Journal impact factor 5.179)

Gastro-intestinal Cancer

SAKK 42/99

Roth AD, Fazio N, Stupp R, Falk S, Bernhard J, Saletti P, Köberle D, Borner MM, Rufibach K, Maibach R, Wernli M, Leslie M, Glynne-Jones R, Widmer L, Seymour M, de Braud F; Swiss Group for Clinical Cancer Research. Docetaxel, cisplatin, and fluorouracil; docetaxel and cisplatin; and epirubicin, cisplatin, and fluorouracil as systemic treatment for advanced gastric carcinoma: a randomized phase II trial of the Swiss Group for Clinical Cancer Research. J Clin Oncol. 2007 Aug 1;25(22):3217-23. (Journal impact factor 13.598)

SAKK 44/00

Herrmann R, Bodoky G, Ruhstaller T, Glimelius B, Bajetta E, Schüller J, Saletti P, Bauer J, Figer A, Pestalozzi B, Köhne CH, Mingrone W, Stemmer S M, Tàmas K, Kornek G V, Koeberle D, Cina S, Bernhard J, Dietrich D, Scheithauer W. Gemcitabine Plus Capecitabine Versus Gemcitabine Alone in Advanced Pancreatic Cancer: a Randomized, Multicenter, Phase III Trial of the Swiss Group for Clinical Cancer Research (SAKK) and the Central European Cooperative Oncology Group (CECOG). J Clin Oncol. 25(16):2212-17, 2007. (Journal impact factor 13.598)

Neuro-Oncology

EORTC

Mauer M, Stupp R, Taphoorn MJB, Coens C, Osoba D, Marosi C, Wong R, De Witte W, Cairncross JG, Efficace F, Mirimanoff RO, Forsyth P, Van Den Bent MJ, Weller M, Bottomley A. The prognostic value of health-related quality-of-life data in predicting survival in glioblastoma cancer patients: Results from an international randomised phase III EORTC Brain Tumour and Radiation Oncology Groups, and NCIC Clinical Trials Group study. Br J Cancer 97 (3): 302-307, 2007. (Journal impact factor 4.459)

Network for CPTC

More H, Humar B, Weber W, Ward R, Christian A, Lintott C, Graziano F, Ruzzo AM, Acosta E, Boman B, Harlan M, Ferreira P, Seruca R, Suriano G, Guilford P. Identification of seven novel germline mutations in the human E-cadherin (CDH1) gene. Hum Mutat. 2007 Feb;28(2):203 (Journal impact factor 6.473)

Further publications

C-PET

Ribi K, Bernhard J, Rufibach K, Thürlimann B, von Moos R, Ruhstaller T, Glaus A, Böhme C. Endocrine symptom assessment in women with breast cancer: what a simple «yes» means. Support Care Cancer. 2007 Dec;15(12):1349-56. (Journal impact factor 1.905)

Gruppo svizzero di oncologia pediatrica SPOG

La ricerca clinica sul cancro nei bambini

■ Del PD Dr. Nicolas von der Weid l Presidente SPOG

Progressi nel 2007

Il miglioramento dei risultati terapeutici dipende essenzialmente dalla ricerca clinica. Data la rarità delle neoplasie infantili, la collaborazione su scala nazionale e internazionale, insieme alla registrazione e il trattamento di pazienti nell'ambito di studi clinici, sono e restano fattori indispensabili. Nel 2007, il 65% dei pazienti curati presso i centri SPOG sono stati ufficialmente inseriti in uno di questi protocolli di ricerca internazionali; il nostro obiettivo per il 2008 è quello di raggiungere almeno una quota del 75%. Tale obiettivo realistico necessita di una straordinaria motivazione delle équipe coinvolte. SPOG ha deciso di aumentare in modo considerevole il budget destinato ai suoi centri regionali sulla base delle loro performance. Tali fondi supplementari devono permettere di garantire l'attività dei coordinatori di studi clinici e nel contempo coprire i costi di notifica dei protocolli di ricerca ai Comitati di Etica locali. Sfortunatamente, l'unificazione di questi comitati a livello nazionale (un solo Comitato Etico (CE) pediatrico per tutti i Paesi ad esempio) resta un'utopia per il momento.

Oltre alla ricerca clinica, SPOG ha posto l'accento negli ultimi anni sulla ricerca epidemiologica, così come sulla ricerca dei risultati (Outcomes Research). Lo strumento principale è il Registro svizzero dei tumori pediatrici (RSTP) che nel giugno 2007 ha ricevuto un'autorizzazione generale simile a quella dei Registri cantonali membri dell'ASRT che gli ha permesso di raccogliere dati provenienti da più fonti e non più solamente dai centri SPOG. Ciò dovrebbe consentire, da un lato, di colmare le lacune di registrazione rilevate nel corso di diverse analisi di «linkage» con i Registri cantonali e, dall'altro, di individuare quali malattie e il motivo per cui non sono trattate in uno dei nostri centri. SPOG resta del parere che tutti i bambini e gli adolescenti affetti da una malattia maligna debbano essere curati e seguiti presso uno dei nove centri specializzati della Svizzera.

Sul piano amministrativo, SPOG ha sviluppato il proprio sito web (http://spog.ch) e ha continuato la sua collaborazione con il SAKK e con il Centro di coordinamento in particolare. Per finire, colgo l'occasione per congratularmi a titolo personale con la PD Dr. Claudia Kühni e il PD Dr. Roland Ammann per il conseguimento del titolo di «PD» presso la Facoltà di Medicina dell'Università di Berna. Congratulazioni!

SPOG: Summary of Activities

■ By PD Dr. Nicolas von der Weid l President SPOG

Clinical Studies

Between November 1st 2006 and October 31st 2007 (cut-off date), 195 children and adolescents under the age of 16 years were newly diagnosed, 85% of them being Swiss residents. Additionally, in the same period, 29 patients had a relapse of their former disease. From the 195 newly diagnosed patients, 127 (65%) have been registered on SPOG-approved collaborative international clinical studies. This result is slightly better than the one obtained in 2006 and is due to the continuous efforts and strong motivation of all SPOG institutions to pass the study protocols through the 14 different cantonal ethics committees as well as the notification procedure of Swissmedic. Overall, about 2000 patients were in active treatment or follow-up in one of the 9 Swiss pediatric oncology units in 2007.

Ongoing clinical research activities of SPOG stayed closely bound to the well established and very active cooperation with international collaborative groups: (Children Oncology Group) COG, BFM/GPOH, SIOP and others: 11 new studies were activated in 2007 resulting in a total of more than 60 open studies; 4 studies were closed to accrual and a total of 33 amendments had to be considered, 22 of which were submitted to both Swissmedic and local ethics committees for approbation.

Two SPOG studies are being conducted on the national level: the first one is the SPOG FN 2003 (PI is PD Dr. Roland Ammann, Kinderklinik Inselspital Bern) started in January 2004. Having reached its planned accrual, the study was closed on December 31st, 2007. Patients have been recruited from all Swiss pediatric oncology units as well as from three German centers (Bonn, Freiburg, Munich). The total recruitment of episodes of fever in neutropenia reached 434; out of them 124 were considered low-risk FN and 70 episodes were randomly assigned to the in- or outpatient regimen. Results are still pending. Within the randomized group, there have been no treatment-associated adverse events reported during the whole course of the study.

The second study is the Late Effects study conducted by SPOG (PI PD Dr. med. Nicolas von der Weid, CHUV, Lausanne) in close collaboration with the Swiss Childhood Cancer Registry (1st Co-PI PD Dr. med. Claudia Kühni, ISPM der Universität Bern). It's a questionnaire-based survey of more than 2500 long-term survivors of childhood cancer, looking at late effects of tumor and its therapy, as well as different aspects of quality of life and type of medical follow-up. Up to now, the response rate is about 65% and

Translational Research: SPOG Tumor bank

Tumor samples collected

Tumor group	2003	2004	2005	2006	2007	Total
Bone tumors	3	9	3	2	1	**18**
CNS tumors	16	18	26	13	11	**84**
Germ cell tumors	–	2	–	1	4	**7**
Kidney tumors	6	9	6	11	5	**37**
Liver tumors	–	3	–	–	2	**5**
Lymphomas	7	6	5	10	9	**37**
Neuroblastomas	5	9	4	6	6	**30**
Normal tissues	2	5	2	–	–	**9**
Pulmonary tumors	–	1	–	–	–	**1**
Rhabdomyosarcoma	2	3	3	2	3	**13**
Other tumors	10	10	12	11	7	**50**
Total	**51**	**75**	**61**	**56**	**48**	**291**

Institutions having sent tumor samples

Origin	2003	2004	2005	2006	2007	Total
Aarau	2	–	–	–	–	2
Bern	10	21	10	4	4	49
Basel	–	2	4	1	2	9
Luzern	–	6	2	1	6	15
St. Gallen	–	–	–	11	10	21
Zurich	39	46	45	39	26	195
Total	**51**	**75**	**61**	**56**	**48**	**291**

data from 950 adult survivors are available, but the study is ongoing. Four abstracts looking at health habits (drug tobacco, alcohol consumptions), educational level and employment status, psychological distress and preferences for follow-up care will be presented shortly at an international conference in Canada as well as at the next congress of SIOP in Berlin in October 2008.

Epidemiological Research

Swiss Childhood Cancer Registry (SCCR)

In 2007, SCCR conducted a series of linkage analyses between its own data and Association of Cancer Registries (ASRT) datasets in the cantons running a registry for more than 10 years. The main findings were that about 15% of all Swiss pediatric cancer patients had been treated outside of comprehensive pediatric oncology centers (i.e. SPOG centers) and that about 6% of all cancer cases known from ASRT were not registered in SCCR. Risk factors for not being treated at a SPOG center were older age (adolescents), bone and soft tissue sarcomas and melanomas. The proportion of patients treated in a SPOG center increased over time. A series of abstracts have been presented on this topic and a summary paper is in preparation.

The quality of SCCR has been recognized at an international level, SCCR being Associate Member of the International Agency for Research on Cancer (IARC). In Switzerland, SCCR is willing to collaborate tightly with the newly created National Institute for Cancer Epidemiology and Registration (NICER). SCCR has been in the limelight, following the paper from the German Registry demonstrating a higher incidence of pediatric cancer, especially acute leukemia, in the vicinity of nuclear power plants in Germany. The Federal Office of Public Health (FOPH) and the Swiss Cancer League (SCL) mandated SCCR to undertake a similar study in Switzerland. With appropriate funding, SCCR will surely be able to satisfy the request but would like to go further as the German study, looking also for possible confounders which could better explain the observed increased risk.

Miscellaneous

At the end of 2007, SPOG activated its own website (http://spog.ch). The layout is similar to the one of SAKK and offers both a public and a private area reserved to SPOG members that is password protected. This internet presence of SPOG is expected to increase its publicity vis-à-vis third parties and stakeholders, especially political authorities, insurance companies, media and pharmaceutical companies, as well as to build a strong link between and a common forum for the nine SPOG institutions.

After the dissolution of SIAK, SPOG decided to maintain its scientific identity and independence from adult medical oncology, while looking for close collaboration

with SAKK in every domain which could be considered equally important for both organizations. A collaboration contract has been established and signed by the executives of SAKK, SPOG and the Coordinating Center.

The traditional SPOG scientific meeting was held again in Locarno on January 25th and 26th, 2007 and was very successful. Twenty papers, mostly from young clinical or lab investigators working in the different SPOG institutions, were presented in short addresses. The scientific level was, as usual, very good and the diversity of presented topics, from epidemiological to clinical and translational research, impressive. SPOG would like to thank the sponsoring companies: CSL Behring, Essex and Glaxo.

The SPOG Scientific Committee met four other times during 2007, once at the Paul Scherrer Institute (PSI) with a very interesting visit of the proton-therapy facility in Villigen. Main discussion topics were related to the collaboration with SAKK, the future NICER and SPOG preferences regarding the future organization of cancer research in Switzerland (Swiss Cancer Network). Another important but somewhat difficult and emotional topic concerned the switch of our Center in Ticino from Locarno to Bellinzona, which became effective on January 1st, 2008. I would like to acknowledge here the great work done by Dr. Luisa Nobile Buetti over the past decades in Locarno. Thanks to her continuous dedication, she was able to offer children and adolescents with cancer the best available therapy enrolling them on clinical studies of the BFM (Berlin-Frankfurt-Munster) and GPOH (Gesellschaft für Pädiatrische Onkologie und Hämatologie), in close collaboration with the SPOG Center in Zurich. On behalf of SPOG, I thank her warmly for all her accomplishments over all these years. I also would like to welcome the new Principal Investigator of SPOG Ticino, Dr. Pierluigi Brazzola, who will take the lead of the unit in Bellinzona at the Pediatric Department. Welcome to the Group!

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Associazione Svizzera Registri Tumori VSKR/ASRT

Registri tumori a sostegno di decisioni politico-sanitarie

■ Della Dr. Silvia Ess l Presidentessa ASRT

I registri cantonali e regionali dei tumori contengono (con un grado di copertura di circa il 60% della popolazione elvetica) dati primari sulle malattie cancerose (incidenza) e le relative caratteristiche del tumore e del paziente. I registri tumori sono un elemento basilare nelle decisioni in materia di politica sanitaria nel campo dei tumori. Pertanto sono necessari dati della più alta qualità.

L'Associazione Svizzera Registri Tumori (ASRT) è stata fondata nel 1992 con l'obiettivo di utilizzare i dati raccolti nei registri regionali per statistiche a livello nazionale. A partire dal 2008 la fondazione NICER (National Institute for Cancer Epidemiology and Registration) deve assumere tali funzioni di coordinamento. Perciò i membri dell'ASRT hanno deciso di sciogliere l'associazione e di trasferire il patrimonio dell'ASRT nella fondazione.

La fondazione NICER è stata istituita l'11 maggio 2007 dall'Associazione Svizzera Registri Tumori e da Oncosuisse. Scopo della fondazione è la promozione ed il sostegno della registrazione dei tumori che colpiscono la popolazione e la ricerca epidemiologica sul cancro in Svizzera. Gli organi della fondazione comprendono il consiglio della fondazione, il consiglio scientifico, il consiglio del registro e il centro di coordinamento come organismo centrale a livello scientifico ed amministrativo ed un organo esterno di revisione. Il Presidente della Fondazione è il prof. Giorgio Noseda. Per la dirigenza del centro di coordinamento è stata scelta la PD Dr. Nicole Probst. Il centro di coordinamento verrà insediato presumibilmente presso l'Institut für Sozial- und Präventivmedizin (Istituto di medicina sociale e preventiva) dell'Università di Zurigo.

Nel periodo 2004–2007 il lavoro dell'ASRT è stato sostenuto finanziariamente dal Segretariato di Stato per la formazione e la ricerca attraverso il SIAK. Nel periodo successivo (2008–2011) i fondi verranno trasferiti in conformità con il messaggio ERI 2008-2011 (messaggio per la promozione dell'educazione, della ricerca e dell'innovazione) all'Ufficio Federale della Sanità Pubblica (UFSP), insieme all'incarico di accelerare il consolidamento dei registri tumori in collaborazione con l'Ufficio Federale di Statistica (UST) e con i cantoni direttamente competenti per la registrazione dei dati e di portare tutto a termine entro la fine del periodo. L'UST deve rivestire un importante ruolo di garante per il mantenimento di standard nazionali e per l'armonizzazione dei dati e deve occuparsi della pubblicazione di dati di tendenza di importanza nazionale. Inoltre è auspicabile che la statistica di incidenza tumorale venga integrata nell'ordinamento statistico.

La concretizzazione del messaggio è stata regolamentata in un contratto tra l'UFSP e la NICER. L'UST e l'UFSP hanno a disposizione in totale 5,3 milioni di CHF, di cui 4,6 milioni di CHF sono stati destinati alla NICER per il periodo dal 2008 al 2011. I fondi sono, secondo contratto, a destinazione vincolata e possono essere utilizzati per l'armonizzazione e l'assicurazione qualità dei dati di epidemiologia tumorale. Viene garantita una stretta collaborazione tra la NICER e l'UST.

Summary of Activities

■ By Dr. Jean-Michel Lutz | Epidemiologist Coordinating Center VSKR/ASRT

Monitoring Cancer in Switzerland

The ASRT/VSKR database has been regularly updated. These data are continuously checked and validated and can be considered definitive when published. Complete data incidence and mortality including the year 2005 has been available on the website www.asrt.ch since the end of 2007. Swiss data are regularly updated in the World Health Organization/International Association of Cancer Registries WHO/IARC database (e.g. Cancer Incidence in Five Continents, Globocan, etc.).

In addition to these routine tasks, many requests for specific data or analysis are frequently received (e.g. incidence, mortality, trends for subsites, prevalence estimates) from registries, cancer leagues, Federal Social Insurance Office FSIO, cantons or individuals. Details on complete ASRT activities can be found on the website (www.asrt.ch).

Meetings, Seminars, Workshops 2007

- Forum on skin melanoma, Geneva, March
- ASRT organized/participated at some major national/international meetings: Group of Latin Language Registries (GRELL) Montreal (Canada), May
- ASRT Workshop in Bern (Treatment coding and Methodology for estimating survival), June
- International Association of Cancer Registries (IACR) and European Network of Cancer Registries (ENCR) annual meeting, Lubljana (Slovenia), September.

On-going Collaborative Projects

- Patterns of Care in Breast Cancer: This study, supported by Oncosuisse-Swiss Cancer League, follows the results of breast cancer survival in Switzerland published by ASRT. The goal is to analyze the reasons for the observed heterogeneity. The data collection phase is still on-going.
- Survival after prostate cancer in Switzerland: comparisons between seven cantons. Communication at the XXXIIe GRELL meeting (Montreal, May).
- EUROCARE 4 and CONCORD programs (European and worldwide comparisons of cancer survivals). Results will be published by the end of this year.

Future of Cancer Registries in Switzerland

After the launch of a National Program against Cancer (2005), we hope to settle the future of cancer epidemiology and cancer registration in Switzerland. With the strong support of Oncosuisse and the Swiss Cancer League, discussions reached a global agreement for setting up the National Institute for Cancer Epidemiology and Registration (NICER), founded in May 2007, which should actively begin its activities in 2008.

NICER will have three objectives. First, to produce basic statistics on cancer surveillance and monitoring (cancer observatory), and second, to allow public health actors to take strategic decisions through evaluation of prevention programs, access to care and care practices. Third, the Institute will support education and training in epidemiology, as well as in collaborative epidemiologic research.

Publications 2007 – ASRT

This does not represent all publications of all ASRT members, but only those including authors from (at least) two different registries and/or those including several registries in the working group.

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Virgili G, Gatta G, Ciccolallo L, Capocaccia R, Biggeri A, Crocetti E, Lutz JM, Paci E: Incidence of Uveal Melanoma in Europe. Ophthalmology 114(12) 2309-2315, 2007.

In addition, Swiss Cancer Registries are involved in all publications using WHO/IARC incidence data (e.g. ACCIS, EUCAN, EUROCIM, GLOBOCAN, Cancer Incidence in Five Continents, etc.), and all publications from EUROCARE and CONCORD programs.

Assemblea semestrale SIAK 2007

■ Della Dr. Stephanie Zülling l Responsabile Partner Relations

Le assemblee semestrali del SIAK nel 2007 hanno avuto luogo il 19 giugno presso il centro congressi Blumenberg di Berna e dal 22 al 23 novembre presso il Centro Congressi di Messe Schweiz a Basilea. In queste occasioni sono stati discussi nuovamente gli obiettivi futuri della ricerca clinica sul cancro in Svizzera.

Per la prima volta l'assemblea semestrale di un giorno è stata effettuata al centro congressi Blumenberg di Berna. La riunione contemporanea dell'assemblea dei delegati SIAK e dei diversi gruppi scientifici ha reso necessarie grandi capacità organizzative per la definizione del luogo in cui tenere l'assemblea semestrale SIAK. Benché sia stato difficile trovare un luogo adatto, una buona alternativa al centro culturale e per i congressi di Berna è stata individuata nel centro congressi Blumenberg, che dispone di una grande sala e di altre sale riunioni per seminari di piccola e media portata. Nelle riunioni dei gruppi scientifici sono stati presentati i risultati degli studi e sono stati discussi nuovi progetti. La partecipazione alle riunioni semi-annuali del SAKK può essere dichiarata come educazione continua FMH per ematologia/oncologia e radiooncologia. Contemporaneamente alla riunione semestrale è stato lanciato il nuovo sito Internet SAKK, che oltre alla nuova grafica offre anche una piattaforma per lo scambio di documenti e una funzione di ricerca (www.sakk.ch).

L'assemblea semestrale di due giorni ha avuto luogo come l'anno precedente presso il Centro Congressi di Basilea. Oltre alle riunioni dei gruppi scientifici, l'assemblea ha affrontato prevalentemente i temi della riorganizzazione e della ristrutturazione della ricerca clinica sul cancro. L'assemblea dei delegati SIAK ha autorizzato, dopo un breve dibattito, il contratto di fusione tra SIAK e SAKK e pertanto lo scioglimento del SIAK senza liquidazione. Il Consiglio di ricerca SAKK aveva approvato la sera prima la revisione degli statuti SAKK, in modo tale che nei giorni seguenti l'assemblea costituente dei membri potesse eleggere il direttivo. Verso mezzogiorno si è tornati ad argomenti scientifici. Nel simposio satellite la Dr. Nathalie Le Bail, Deputy Head of Oncology & Exploratory Pharmacology di sanofi-aventis SA e il Dr. Michael Lahn, Medical Advisor Science & Technology di Eli Lilly hanno presentato nuove sostanze per la cura dei tumori.

Un altro momento importante è stata l'assegnazione del premio SIAK/Pfizer 2007 e del SAKK/AMGEN Research Grant. Il Dr. Martin Buess dell'oncologia medica di Basilea è stato insignito del premio SIAK/Pfizer, un riconoscimento per i risultati straordinari nella ricerca sul cancro, per il suo lavoro dal titolo «Characterization of heterotypic interaction effects in vitro to deconvolute global gene expression profiles in cancer». Il Dr. Buess ha studiato l'interazione di cellule cancerose del seno con circostanti cellule stromali (cellule connettivali). I risultati confermano che tali interazioni possono favorire la progressione del tumore, molto probabilmente attraverso un'ulteriore emissione di determinate sostanze messaggere. Il SAKK/AMGEN Research Grant è andato ai ricercatori Dr. med. Dr. phil. Andreas Wicki e PD Dr. Christoph Mamot, entrambi in servizio presso l'ospedale universitario di Basilea. Il lavoro premiato dal titolo: «Targeting of VEGFR-3 expressing endothelial tip cells as a novel anti-angiogenic approach» parla dell'utilizzo di una tecnica elaborata da entrambi i ricercatori (=immunoliposomi) per il trasporto mirato di sostanze chemioterapiche e geni terapeutici alle cellule espressive VEGFR-3. Tali cellule (endothelial tip cells) sembrano giocare un ruolo importante nella formazione di un tumore e l'ipotesi è che possano rappresentare un buon punto di partenza per una terapia mirata. Congratulazioni vivissime ai vincitori!

Dr. Andreas Wicki e PD Dr. Christoph Mamot (in primo piano), vincitori del SAKK/AMGEN Research Grant

Nel successivo simposio «IL NUOVO SAKK: strategia, struttura e futuro» il Presidente del SAKK, il prof. Richard Herrmann, ha illustrato ai presenti i cambiamenti strutturali e organizzativi che sono stati compiuti durante questa assemblea semestrale. Nel suo intervento ha illustrato le strutture semplificate e ha presentato i nuovi membri SAKK e del consiglio direttivo. Ha concluso con uno sguardo agli orientamenti futuri del SAKK.

Al termine della prima giornata dell'assemblea semestrale è stata messa in scena l'opera teatrale interattiva «Alles Liebe», che tematizza l'impotenza negli ammalati di cancro, nei loro parenti e amici ma anche nei medici e negli infermieri. Nella prima parte della rappresentazione il gruppo teatrale Knotenpunkt di Zurigo ha messo in scena situazioni tipiche della quotidianità dei pazienti. In seguito il pubblico ha avuto la possibilità di suggerire cambiamenti alle singole scene. Gli attori reagivano in base alla situazione e concedevano agli spettatori, ora coinvolti anch'essi nella rappresentazione, di sperimentare direttamente gli effetti dei propri modi di agire. Il pubblico era stimolato a riflettere sul proprio ruolo e sul proprio comportamento nei rapporti con i malati di cancro e ad acquistare pertanto maggiore consapevolezza.

Nel pomeriggio successivo si sono riuniti i gruppi di progetto SAKK sui carcinomi mammari e altri gruppi di lavoro. Nel complesso l'ultima assemblea semestrale è stato un successo, dato confermato anche dal grande numero di partecipanti. Le prossime assemblee semestrali si terranno interamente sotto l'egida del SAKK e speriamo che avranno sempre lo stesso successo.

Assegnazione del SAKK-Pfizer-Award 2008
Premio per la qualità nella ricerca clinica sul cancro

Il regolamento di partecipazione per l'assegnazione del premio SAKK/Pfizer 2008 può essere richiesto a:

Prof. Richard Herrmann, Presidente SAKK
SAKK Centro di coordinamento
Effingerstrasse 40
3008 Berna

Dr. Martin Buess (al centro), vincitore del premio SIAK/Pfizer

Resoconto annuale 2007

Resoconto annuale dal 1° gennaio al 31 dicembre (in CHF)	**SAKK**	**VSKR**	**SPOG**
REDDITO DI ESERCIZIO			
Contributi per la ricerca SBF*	5 266 800	900 900	449 460
Contributi per la ricerca KLS/KFS**	295 000		
Contributi per la ricerca SSKK***	100 000		
Altri contributi per la ricerca	145 865	251 451	
Oncosuisse	224 996		
Ricavi collaborazioni industriali	2 319 453		
Redditi bollettino sul cancro	352 655		
Redditi vari	211 565		1 220
TOTALE REDDITO DI ESERCIZIO	**8 916 334**	**1 152 351**	**450 680**
SPESE DI ESERCIZIO			
Costi per studi vari	311 800		3 200
Contributi per la ricerca SPOG [1]	449 460		
Contributi per la ricerca ASRT [2]	900 900		
Contributi per la ricerca IBCSG [3]	250 000		
Contributi per la ricerca Regioni/Stazioni	2 198 918	882 841	244 625
Costi di trasferta e viaggi di rappresentanza	199 902	5 510	1 085
Altre spese di esercizio	154 902	4 000	
TOTALE SPESE DI ESERCIZIO	**4 465 881**	**892 351**	**248 910**
Subtotale 1	4 450 452	260 000	201 770
COSTI DI COORDINAMENTO			
Costi per il personale	3 160 505	332 117	100 855
Altri costi di coordinamento	975 575	12 032	33 323
TOTALE COSTI DI COORDINAMENTO	**4 136 080**	**344 149**	**134 178**
Subtotale 2	314 372	–84 149	67 591
RISULTATO FINANZIARIO			
Reddito finanziario	50 619	398	237
Oneri finanziari	–2 195	–97	–105
TOTALE RISULTATO FINANZIARIO	**48 424**	**301**	**132**
Subtotale 3	362 796	–83 848	67 723
RISULTATO NON OPERATIVO STRAORDINARIO			
Scioglimento di accantonamenti non necessari	77 900		
TOTALE RISULTATO NON OPERATIVO STRAORDINARIO	**77 900**	**–**	**–**
RISULTATO COMPLESSIVO	**440 696**	**–83 848**	**67 723**

* Segretaria di stato per l'educazione e la ricerca (mediante il SIAK i capitali vanno alle relative associazioni, come de accordo sulle prestazioni con l'unione)

** Lega contro il cancro/Ricerca svizzera contro il cancro

*** Fondazione svizzera per la ricerca clinica contro il cancro

[1] Gruppo Onco-Pediatrico Svizzero SPOG

[2] Associazione Svizzera Registri Tumori ASRT

[3] International Breast Cancer Study Group IBCSG

Indirizzi

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

SAKK Coordinating Center
Effingerstrasse 40
3008 Bern
Tel 031 389 91 91
Fax 031 389 92 00
www.sakk.ch
sakkcc@sakk.ch

Relazione bancaria (per offerte)
Banca Cantonale di Berna
BEKB 42 4.106.071.25

Schweizerische Pädiatrische Onkologie Gruppe SPOG
Groupe Suisse d'Oncologie Pédiatrique SPOG
Gruppo Onco-Pediatrico Svizzero SPOG

SPOG Sekretariat
Effingerstrasse 40
3008 Bern
Tel 031 389 91 89
http://spog.ch

Vereinigung Schweizer Krebsregister VSKR
Association Suisse des Registres des Tumeurs ASRT
Associazione Svizzera Registri Tumori ASRT

Coordinating Center
c/o RGT
Bd de la Cluse 55
1205 Genève
www.asrt.ch
www.vskr.ch

Contributi dal settore pubblico e d'altri
Segreteria di Stato per l'educazione e la ricerca SER
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