SAKK

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

The Swiss Oncology Research Network

Rapporto annuale

La versione PDF del rapporto annuale 2010 è disponibile su
www.sakk.ch

Indice

Prof. Dr. Beat Thürlimann | Presidente del SAKK

La nostra relazione annuale illustra le attività svolte dal SAKK l'anno passato. L'attività scientifica verso l'esterno è visibile dai nuovi studi attivati, dalle numerose relazioni tenute a congressi internazionali e dalle pubblicazioni su prestigiose riviste mediche specializzate.

L'incontro di addio con il Prof. Richard Herrmann, presidente uscente del SAKK, è stato un momento straordinario. Per l'occasione i gruppi di progetto hanno presentato i risultati degli studi più importanti realizzati sotto la sua presidenza. Impressionante il numero di contributi provenienti da tutti gli ambiti oncologici pubblicati sulle più note riviste specializzate di oncologica clinica.

Importante, per l'ulteriore sviluppo del SAKK e di tutta la ricerca clinica svizzera in generale, è il crescente networking nell'ambito della politica della ricerca. Il Dr. Peter Brauchli, amministratore del SAKK, ed io continueremo a dedicare a questo aspetto del nostro lavoro la dovuta attenzione. Nei prossimi anni la ricerca clinica svizzera dovrà affrontare alcune sfide che offriranno, comunque, opportunità per avviare cambiamenti in positivo. Nella seconda metà dell'anno, fra le nostre attività vi è stata quella di far sentire la nostra voce sulla nuova legislazione sulla ricerca sull'essere umano. Insieme ad altre istituzioni svizzere per la lotta contro il cancro (Gruppo d'Oncologia Pediatrica Svizzera GOPS, Ricerca Svizzera contro il Cancro RSC, Lega Svizzera contro il Cancro LSC e National Institute of Cancer Epidemiology and Research NICER), siamo riusciti a far arrivare le nostre istanze alla Commissione del Consiglio nazionale.

All'interno del SAKK continua il cammino di professionalizzazione e sta andando avanti sistematicamente anche il programma volto ad accrescere l'efficienza. L'obiettivo è quello di ottimizzare i processi all'interno del SAKK, in modo da accelerare i tempi di attivazione dei vari progetti. Una nuova soluzione IT ci sarebbe di aiuto nel raggiungere tale scopo.

Siamo quindi ben attrezzati per affrontare con successo l'anno nuovo. Colgo l'occasione per ringraziare in questa sede tutti coloro che, dall'interno o dall'esterno, hanno contribuito con il loro prezioso lavoro – in particolare il Dr. Peter Brauchli, direttore del SAKK, e i suoi dirigenti – ai risultati della nostra istituzione.

Il mio ringraziamento va anche a tutti coloro che ci hanno sostenuto idealmente, politicamente e finanziariamente, in particolare la Segreteria di Stato per l'educazione e la ricerca SER, la Fondazione Svizzera per la Ricerca sul Cancro, la Lega Svizzera contro il Cancro, la Fondazione Svizzera per la Ricerca Clinica sul Cancro nonché l'industria per la collaborazione fornita nella realizzazione dei progetti.

Dott. Peter Brauchli | Direttore del SAKK

Chi siamo

Il Gruppo Svizzero di Ricerca Clinica sul Cancro (SAKK), come istituto universitario di ricerca, è un'organizzazione no-profit che effettua autonomamente studi clinici sul cancro. Negli scorsi anni il SAKK ha messo a punto, sviluppato, realizzato e valutato studi clinici, partecipando inoltre a vari processi politici e mettendo le proprie conoscenze ed esperienze anche a disposizione di altri settori della ricerca clinica. Grazie all'unicità della sua struttura, il SAKK è in grado di offrire ai suoi 17 membri la possibilità di effettuare ricerca clinica ai massimi livelli. Gli studi del SAKK vengono condotti, in tutto, in oltre 50 strutture svizzere e in ospedali esteri, che risulta in un straordinario network di clinici, ricercatori e collaboratori motivati. Nell'incontro di addio a Prof. Dr. Richard Herrmann, tenutosi nel giugno scorso, si sono messi in evidenza l'impressionante sviluppo del network negli ultimi sei anni, la prestazione dei ricercatori e la grande motivazione che guida il loro lavoro.

Comitato direttivo

Molti sono stati nel 2010 i cambiamenti intervenuti in seno al Comitato direttivo del SAKK. Al termine dei sei anni di mandato – durata massima prevista – il Prof. Dr. Richard Hermann ha lasciato la presidenza, e a luglio gli è subentrato il Prof. Dr. Beat Thürlimann. Anche il Prof. Dr. Daniel Betticher, il Prof. Dr. Martin Fey, il Prof. Dr. Holger Moch e il Dr. Arnaud Roth, libero docente, sono usciti dal Comitato, che ora è composto dal Prof. Dr. Markus Borner, dalla Dr. Viviane Hess, libera docente, dal Dr. Miklos Pless, libero docente, e dal Prof. Dr. Achim Weber. Durante il ritiro annuale il Comitato ha discusso gli obiettivi dei prossimi anni. In particolare, ha precisato le linee strategiche, del resto già formulate nella domanda presentata alla Segreteria di Stato per l'educazione e la ricerca SER per l'esercizio 2013–2016.

Il SAKK focalizzerà la propria attività sui settori
- Cancro al seno
- Tumori gastrointestinali
- Leucemie
- Cancro ai polmoni
- Linfomi
- Tumori dell'apparato urogenitale
- Nuovi farmaci anticancro

Il SAKK si sforzerà, inoltre, di estendere la ricerca clinica anche a settori che non rientrano nei gruppi di progetti prioritari, quali, ad esempio, i tumori della testa e del collo, i sarcomi, i melanomi, i tumori del sistema nervoso centrale e i tumori ginecologici.

In futuro, negli studi del SAKK verranno presi in considerazione, oltre ai concept terapeutici, anche questioni specifiche dei settori prevenzione, ricerca nel campo dei servizi sanitari, assistenza dopo la terapia, trattamento di fasce specifiche della popolazione (ad esempio, anziani) e cure palliative. Obiettivi dichiarati sono anche quelli di offrire ad un maggior numero di pazienti la possibilità di partecipare agli studi clinici e di assumere sempre più un ruolo guida nella realizzazione di studi internazionali.

Gruppi di progetto, sezioni, gruppi di lavoro

Le attività del network SAKK sono numerose. Il Comitato direttivo si è trovato di fronte a tante nuove proposte di studio. Questo spirito innovativo è determinante se vogliamo centrare i nostri obiettivi; l'aumento della richiesta di progetti non può che rallegrarci. Alcuni gruppi hanno avuto un nuovo presidente, e durante l'assemblea semestrale di novembre è stato insediato un nuovo gruppo di lavoro per i tumori ginecologici. Per poter fare più ricerca in questo importante campo, è di fondamentale importanza che oncologi e ginecologi collaborino tra di loro.

Nel 2010 è stato anche introdotto il nuovo regolamento che riguarda i membri con diritto di voto nei gruppi di progetto. L'esercizio del diritto di voto in un gruppo di progetto è vincolato alla partecipazione attiva agli studi e all'inclusione di pazienti valutabili.

Attività di studio 2010

Lo scorso anno il SAKK ha incluso 832 pazienti in 44 studi clinici; 546 di questi sono stati reclutati nell'ambito di studi sviluppati dallo stesso SAKK. L'attività di studio è stata nuovamente ampliata. La percentuale di studi effettuati all'estero, invece, per i quali il protocollo non è stato sviluppato dal Centro di coordinamento del SAKK, è – seppur di poco – ulteriormente diminuita. Complessivamente, il Comitato direttivo ha approvato, nella fase di verifica finale, nove studi clinici. Sei proposte sono state bocciate già in fase di initial assessment, mentre uno studio in final assessment. Altri tre studi sono rimasti bloccati in fase di initial assessment, poiché le industrie o non hanno offerto sostegno oppure lo hanno ritirato. Siamo lieti a questo proposito di comunicarvi che il SER ha confermato la nostra istituzione soddisfa tutti i requisiti relativi al processo di valutazione progetti in materia di procedura decisionale e separazione dei poteri.

Nel 2010 il SAKK ha sviluppato 13 nuovi studi, sette dei quali sono già attivati. Sono già state pubblicate 11 relazioni principali su studi scientifici ai quali il SAKK ha partecipato come responsabile o ai quali ha dato un contributo determinante.

Per sette studi il SAKK ha reclutato pazienti anche all'estero – Germania, Francia, Italia, Belgio, Ungheria, Polonia e Olanda. Per alcuni studi, l'apertura di nuovi centri nell'UE procede velocemente e porta subito pazienti da inserire nei programmi. Per altri progetti, invece, l'apertura di centri all'estero comporta, a causa della complessità della logistica, grosse spese e ritardi.

Per la maggior parte degli studi, la partecipazione dei pazienti è stata alquanto soddisfacente. Una sfida, comunque, è rappresentata dagli studi con reclutamento lento dei pazienti; per poter intervenire con tempestività, si segue la problematica da vicino e si prende contatto con i centri participanti. Per fortuna, le biobanche che creiamo nell'ambito degli studi clinici, vengono utilizzate sempre più di frequente. Appena sorge qualche interrogativo interessante, il materiale biologico raccolto viene esaminato e messo in relazione con i dati clinici. Per fare questo collaboriamo anche con la biobank-suisse. Va notato che si analizzano sempre più questioni cliniche che non riguardano i farmaci.

Formazione continua

Nel 2010 il SAKK ha tenuto due corsi di aggiornamento per medici sperimentatori e uno per i Clinical Research Coordinators, allo scopo di professionalizzare il lavoro di ricerca clinica. Il simposio State of the Art in Oncology Research era già alla sua quarta edizione; questa volta era incentrato sul tema «La medicina personalizzata in oncologia». Quest'ultima è un argomento su cui si discute molto; i relatori delle varie specializzazioni hanno ricordato che questo tipo di medicina non è certamente una novità, ma che l'utilizzo dei biomarcatori apre nuove frontiere per le terapie e la ricerca. Gli incontri sono stati seguiti con vivo interesse e hanno registrato una buona partecipazione dei vari gruppi professionali.

Cooperazioni

Nel campo della ricerca clinica – uno scenario che muta molto rapidamente – per il SAKK è indispensabile posizionarsi in modo chiaro e difendere i propri interessi. E' per questo che cerchiamo di estendere la collaborazione ad altri gruppi, anche per far valere le nostre istanze in modo più efficace a livello politico e avvicinare un pubblico sempre più vasto alla ricerca clinica.

Siamo riusciti a potenziare la collaborazione con la Swiss Clinical Trial Organisation (SCTO) sul piano operativo. Il SAKK è lieto di poter trasmettere la propria esperienza e di trarre vantaggio dai processi produttivi della SCTO. Si è visto che le due organizzazioni funzionano in modo diverso e perseguono obiettivi diversi, ma che condividono un interesse comune, che è quello di potenziare la ricerca clinica in Svizzera.

Bilancio annuale

Il bilancio annuale 2010 ha chiuso in rosso, una situazione che si era già prospettata a metà dell' anno. Il deficit è stato causato dalle mancate entrate conseguenti a ritardi nell'attivazione di studi e dalla lentezza del reclutamento di pazienti. Un'analisi della situazione ha già portato all'adozione di correttivi, come ad esempio un migliore sostegno ai progetti e una maggiore severità nel rispetto delle scadenze da parte del personale e di collaboratori del network. In futuro, quando il Comitato direttivo deciderà di avviare uno studio, ne valuterà più attentamente la fattibilità dal punto di vista temporale. Esso ha già preso la decisione strategica di investire nell'acquisizione di mezzi finanziari elargiti da terzi.

Ciò che incide particolarmente sulle spese è l'assunzione dei costi, che ci sarebbero comunque, anche nell'ambito delle terapie standard. Sulla base dell'attuale interpretazione delle disposizioni di legge, lo sponsor di uno studio clinico è costretto, parzialmente, a sostenere anche i costi delle cure, delle misure e delle terapie standard dei pazienti che partecipano allo studio.

Electronic Data Capture EDC
Nel 2010 sono stati implementati e resi accessibili ai centri cinque studi sviluppati nell'ambito della soluzione EDC SINATRAS, elaborata internamente. Abbiamo dovuto però constatare, nel corso dell'anno, che questa soluzione può oramai soddisfare le esigenze attuali solo a prezzo di grandi investimenti. Dopo un'attenta valutazione abbiamo deciso di adottare, quale nuova soluzione software EDC, il sistema a marchio commerciale secuTrial®, che in futuro verrà utilizzato anche dalle Clinical Trial Units.

Programma oncologico nazionale
L'elaborazione del nuovo Programma nazionale di lotta contro il cancro (NKP) per il periodo 2011–2015 è in fase molto avanzata e sarò pubblicato nel 2011. L'NKP è uno strumento di coordinamento politico, che interessa tutta la Svizzera, nato con lo scopo di analizzare, prevenire, effettuare la diagnosi precoce e la terapia del cancro, nonché di attenuare le conseguenze di tale malattia. Il SAKK ha elaborato i capitoli Ricerca e Terapia e sarà il responsabile principale per l'ambito della ricerca. L'NKP è uno strumento importante per far avanzare a livello politico un numero crescente di processi e per accrescere la visibilità politica del SAKK. Il progetto, per il network svizzero per la lotta nazionale contro il cancro, è una delle priorità dei prossimi anni. Nell'ambito dell'NKP si è creata una preziosa e fruttuosa collaborazione fra le varie organizzazioni che aderiscono alla Lega svizzera contro il cancro.

Lavoro politico
Insieme alla Lega svizzera contro il cancro e alla Oncosuisse, il SAKK è impegnato, nell'ambito del processo politico, a sviluppare la legge sulla ricerca sull'essere umano. Il SAKK ha avviato anche altri processi per semplificare la ricerca clinica, affrontando anche la problematica dell'assunzione dei costi di cure e trattamenti nell'ambito degli studi clinici. Qui si vede chiaramente che il SAKK è un'istituzione universitaria con esperienza pratica pluriennale nello svolgimento dei studi clinici, che viene consultata e tenuta in considerazione dalle istituzioni politico-sanitarie del Paese.

Ci sono stati incontri molto importanti e proficui con il consorzio delle Commissioni etiche (AGEK), la Swissmedic, l'Ufficio federale della sanità pubblica (UFSP), la Segreteria di stato per l'educazione e la ricerca (SER), il Fondo nazionale svizzero (FNS) e la Swiss Clinical Trial Organisation (SCTO).

Centro di coordinamento
Presso il Centro di coordinamento del SAKK abbiamo avviato, nel 2010, una fase di consolidamento. Per far fronte al crescente numero di studi da sviluppare e al lavoro che questi comportano, a fine 2010 il numero di collaboratori fissi del SAKK è salito a 52,2 in più (43,60 FTE). La nuova responsabile del Dipartimento IT è ora Cornelia Kruschel, che ha assunto la carica nell'aprile del 2010. E' stata creata la nuova figura di Medical Advisor, che deve assistere il responsabile dello studio nello sviluppo dei piani e deve monitorare, insieme al personale non medico del Centro di coordinamento e al Presidente, la sicurezza dei pazienti. Il Dr. Arnoud Templeton lavora come oncologo presso l'Ospedale cantonale di San Gallo, e al 50 % presso il Centro di coordinamento.

Straordinario è stato anche l'impegno dimostrato dai collaboratori di tale Centro. Ringrazio di tutto cuore i responsabili del Dipartimento e i loro team per il lavoro indefesso compiuto a servizio del SAKK.

Membri del Comitato direttivo

Presidente
Prof. Dr. Beat Thürlimann
Ospedale Cantonale
di San Gallo

Vicepresidente
Dr. Roger von Moos
Ospedale Cantonale
di Coira

Prof. Dr. Stephan Bodis
Ospedale Cantonale
di Argovia

Prof. Dr. Markus Borner
Centro Ospedaliero
di Bienna
Inselspital di Berna

PD Dr. Yves Chalandon
Clinica Universitaria
di Ginevra

Prof. Dr. Michele
Ghielmini
Ospedale Regionale
Lugano

Dr. Viviane Hess,
libera docente,
Clinica Universitaria
di Basilea

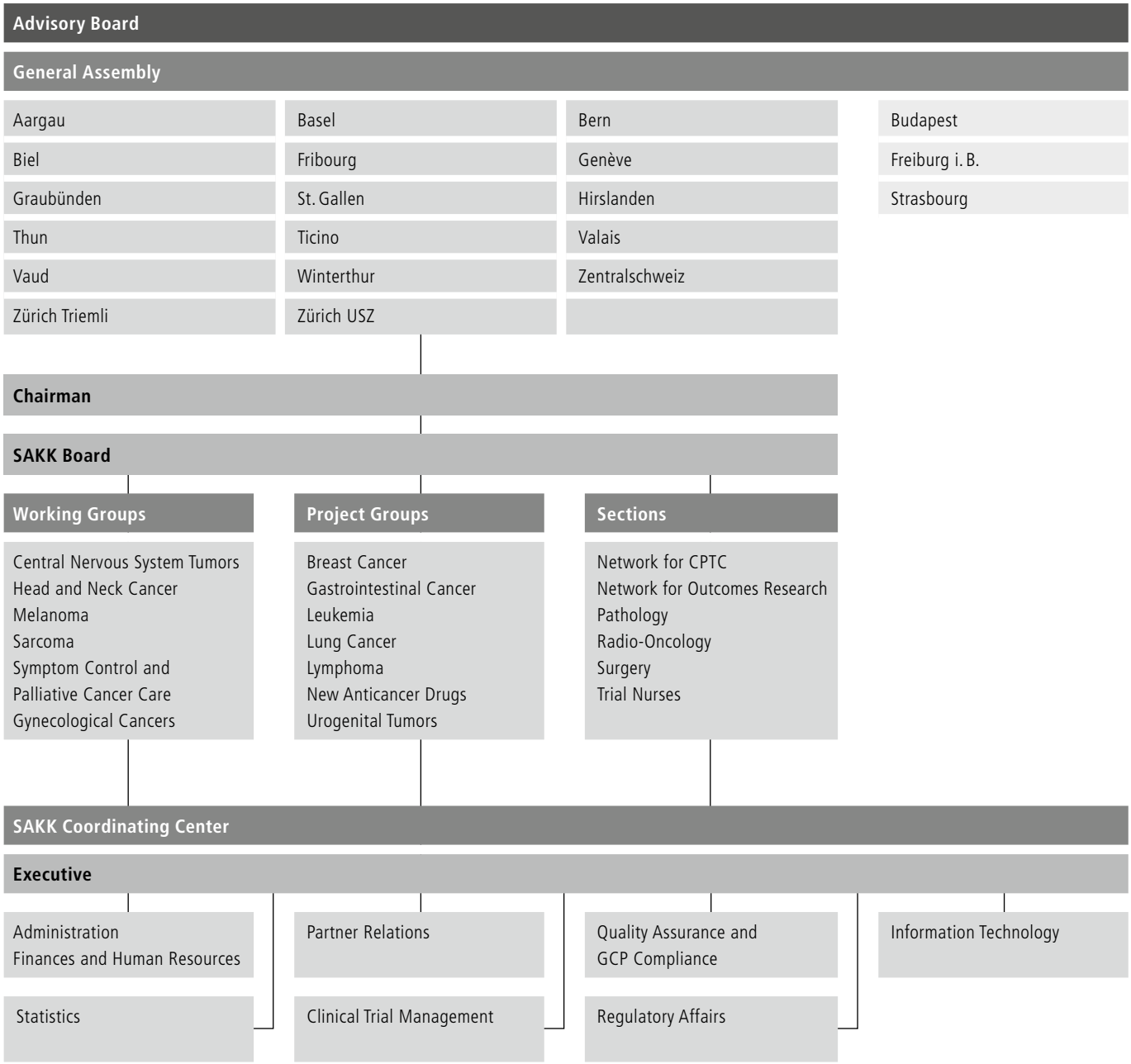
Prof. Dr. Walter Richard
Marti
Ospedale Cantonale
di Argovia

Dr. Miklos Pless,
libero docente
Ospedale Cantonale
di Winterthur

Prof. Dr. Christoph Renner
Clinica Universitaria
di Zurigo

Prof. Dr. Achim Weber
Clinica Universitaria
di Zurigo

Organigram Swiss Group for Clinical Cancer Research (SAKK)



8 | Quadro dirigenziale, onorificenze e promozioni all'interno del SAKK

Primari
- Prof. Dr. Stefan Aebi, primario di Oncologia medica, Ospedale cantonale di Lucerna
- Prof. Dr. Jakob Passweg, primario di Ematologia, Clinica universitaria di Basilea

Direzione medica
- Prof. Dr. Christoph Driessen, dirigente medico, Ospedale cantonale San Gallo
- Prof. Dr. Jens Huober, dirigente medico, Brustzentrum, Ospedale cantonale San Gallo
- Dr. Florian Strasser, libero docente, dirigente medico, Ospedale cantonale San Gallo

Capiclinica
- Dr. Federica Chiesa, capoclinica, Brustzentrum, Ospedale cantonale San Gallo
- Dr. Markus Jörger, capoclinica, Brustzentrum, Ospedale cantonale San Gallo
- Dr. Salomé Riniker, capoclinica, Brustzentrum, Ospedale cantonale San Gallo

Nomine
- Prof. Dr. Jane Apperley, Chair of the Department of Haematology, Department of Medicine, Imperial College London: membro del Comitato scientifico SAKK
- Prof. Dr. Markus Borner, primario di Oncologia medica, Spitalzentrum Bienna e dirigente medico di Oncologia medica, Inselspital, Berna: membro del Comitato direttivo SAKK
- Dr. Mathias Fehr, libero docente, primario Frauenklinik, Ospedale cantonale di Frauenfeld: copresidente SAKK, Gruppo di lavoro Tumori ginecologici
- Dr. Viviane Hess, libera docente, capoclinica di Oncologia, Clinica universitaria di Basilea: membro del Comitato SAKK
- Dr. Andreas Hottinger, Hôpital Universitaire di Ginevra: presidente Gruppo di lavoro Tumori del sistema nervoso centrale
- Dr. Michael Montemurro, Centre Pluridisciplinaire d'Oncologie, CHUV di Losanna: presidente del Gruppo di lavoro Tumori gastrointestinali
- Prof. Dr. Jakob Passweg, primario di Ematologia, Clinica universitaria di Basilea: presidente della Lega svizzera contro il cancro
- Dr. Miklos Pless, libero docente, primario di Oncologia medica, Ospedale cantonale di Winterthur: membro del Comitato direttivo SAKK
- Prof. Dr. Cristiana Sessa, Ospedale San Giovanni Bellinzona: copresidente SAKK, Gruppo di lavoro Tumori ginecologici
- Prof. Dr. Simon Thompson, Director MRC Biostatistics Unit Institute of Public Health, Cambridge: membro del Comitato scientifico SAKK
- Dr. Roger von Moos, dirigente medico, Ospedale cantonale di Coira, vicepresidente SAKK
- Prof. Dr. Achim Weber, dirigente medico, Istituto di patologia clinica della Clinica universitaria di Zurigo: membro del Comitato SAKK e presidente della Sezione Patologia SAKK
- Prof. Dr. Franz Zimmermann, Istituto di Radio-oncologia, Clinica universitaria di Zurigo: presidente SAKK del Gruppo di lavoro Tumori alla testa e al collo

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

Assemblea semestrale di giugno

Il 17 giugno 2010 si è tenuta a Berna l'assemblea semestrale estiva del SAKK; vi hanno partecipato oltre 250 oncologi specializzati, rappresentanti delle case farmaceutiche e collaboratori del Centro di coordinamento del SAKK.

In sede di assemblea i partecipanti hanno approvato il bilancio annuale e dato il discarico ai membri del Comitato direttivo. L'assemblea ha eletto poi due nuovi membri del Comitato in sostituzione del Prof. Dr. Beat Thürlimann dell'Ospedale Cantonale di San Gallo, presidente uscente, e del Prof. Dr. Martin Fey dell'Inselspital di Berna. Nuovi membri del Comitato del SAKK sono stati nominati la Dr. Viviane Hess, libera docente, della Clinica universitaria di Basilea, e il Prof. Dr. Markus Borner, del Centro ospedaliero di Bienna e dell'Inselspital di Berna.

In occasione dell'assemblea semestrale, il SAKK ha organizzato un incontro di addio per il Prof. Dr. Richard Herrmann, che ha lasciato l'incarico di presidente del SAKK a giugno, dopo essere rimasto in carica per sei anni, durata massima del mandato. Il Prof. Dr. Beat Thürlimann, suo successore, gli è subentrato nella carica il 1° luglio 2010.

Prof. Dr. Markus Borner

PD Dr. Viviane Hess

Il Dr. Michael Montemurro ed il Prof. Dr. John Prior con
Helga Meier ed il Prof. Urs Metzger del Comitato del Premio.

Assemblea semestrale di novembre
L'assemblea del semestre invernale del SAKK si è tenuta a Basilea nei giorni 25 e 26 novembre 2010. Oltre alle varie sedute dei gruppi di ricerca, hanno avuto luogo anche il simposio SAKK e il simposio satellite, sponsorizzato dalle case farmaceutiche Boehringer di Ingelheim e Roche Pharma (Svizzera).

All'apertura del simposio SAKK, il Gruppo GIST Svizzera ha conferito ai due ricercatori oncologici, il Dr. Michael Montemurro e il Prof. Dr. John Prior del CHUV di Losanna, il premio GIST 2010.

Il riconoscimento ha una dotazione in denaro di 10 000 franchi svizzeri e viene assegnato ogni anno per attività scientifiche che contribuiscono a migliorare la terapia dei tumori stromali gastrointestinali (GIST). Durante il simposio SAKK, iniziato subito dopo, il presidente di Oncosuisse, Prof. Dr. Richard Herrmann, ha presentato il Programma nazionale svizzero di lotta contro il cancro (NKP) per il periodo 2011–2015.

Durante l'assemblea dei soci SAKK sono stati eletti due nuovi membri e riconfermati quattro membri del Comitato direttivo. I nuovi eletti sono il Dr. Miklos Pless, libero docente, dell'Ospedale cantonale di Winterthur, e il Prof. Dr. Achim Weber, della Clinica universitaria di Zurigo. Il Prof. Weber è stato eletto presidente dalla sezione Patologia del SAKK, e la rappresenta in seno al Comitato direttivo.

L'assemblea, inoltre, ha eletto all'unanimità due nuovi membri del Comitato scientifico: l'ematologa Jane Apperley, dell'Imperial College di Londra, UK, e lo statistico Simon Thompson dell'MRC Biostatistics Unit di Cambridge, UK. I nuovi eletti vanno a sostituire Andreas Neubauer della Clinica universitaria di Marburg, Germania, e Mahesh Parmar, Medical Research Council, Londra, UK.

Infine, nel corso dell'appuntamento semestrale invernale è stato insediato un nuovo gruppo di lavoro per i tumori ginecologici.

Prof. Dr. Achim Weber

PD Dr. Miklos Pless

Prof. Dr. Richard Herrmann

Ringraziamento al Prof. Dr. Richard Herrmann

Il Prof. Dr. Richard Herrmann ha assunto la presidenza del SAKK nel giugno del 2004, in un momento di crisi della ricerca clinica svizzera sul cancro. La crisi era sorta dopo l'introduzione della nuova legge sui farmaci contro le cui norme era andato a cozzare il SAKK. A Richard Herrmann la nostra istituzione stava particolarmente a cuore; egli era consapevole dell'importanza dell'attività del SAKK per la società e non avrebbe consentito che venisse abbandonata. Il professore ben conosceva il potenziale della ricerca sul cancro; si assunse l'impegno di dedicarle energia e tempo per riportare il SAKK sulla strada del successo.

Dobbiamo a Herrmann se il SAKK è oggi quel che è: un'istituzione forte, con un proprio Centro di coordinamento. Il nostro ex presidente ne ha sostenuto l'ampliamento e ne ha aumentato sensibilmente la produttività. Oggi tale Centro viene percepito come centro di competenza. Il SAKK ha ritrovato la propria collocazione fissa nell'ambito della ricerca clinica, e oggi è un'organizzazione di riferimento. Sotto la sua egida, i clinici di varie discipline portano avanti progetti comuni multimodali di ricerca sempre più numerosi. Ora gli ospedali non eseguono più gli studi perché costretti, ma perché la ricerca clinica è comunque un'attestazione di qualità, di valenza universale, e che può anche aiutare l'Istituto stesso e i ricercatori ad ottenere riconoscimenti internazionali. La ricerca clinica professionale viene vista sempre più anche come misura di garanzia di sicurezza e direttamente al servizio dei pazienti.

In questi sei anni di presidenza, Richard Herrmann ha guidato la nostra istituzione con avvedutezza e lungimiranza, e anche come persona è un luminoso esempio da imitare. Grazie a lui abbiamo capito che cosa significhi assumersi delle responsabilità e perseguire con tenacia un obiettivo. Ringraziamo Richard Herrmann per tutto quello che ha fatto per il SAKK: per come lo ha guidato, a nome dei collaboratori del Centro di coordinamento, dei ricercatori e dei pazienti.

By Ursula Kühnel, Head Clinical Trial Management

Summary of Activities

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

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

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

Trials open for accrual in 2010

Urogenital Cancers

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

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

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

Lung Cancer

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

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

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

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

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

Breast Cancers

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

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

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

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

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

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

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

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

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

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

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

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

Leukemias

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

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

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

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

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

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

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

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

Lymphomas

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

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

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

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

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

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

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

Gastrointestinal Cancers

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

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

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

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

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

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

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

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

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

Supportive Care

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

New Drugs

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

Further projects 2010

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

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

Trials activated in 2010

Urogenital Cancers

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

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

Lung Cancer

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

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

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

Breast Cancers

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

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

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

Leukemias

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

Lymphomas

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

Gastrointestinal Cancers

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

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

New Drugs

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

Trials closed in 2010

Urogenital Cancers

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

Leukemias

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

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

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

Lymphomas

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

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

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

Gastrointestinal Cancers

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

New Drugs

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

Project Group Breast Cancer


1


2

Presidents:

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

Objectives

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

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

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

Activities

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

Trials Activated in 2010

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

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

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

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

Strategic elements for the next two years

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

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

Portfolio Plan

These protocols are in preparation by the group:

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

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

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

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

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

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

Collaboration with/participation in other groups

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

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

Project Group Gastrointestinal Cancer

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

Objectives

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

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

Activities

Trials activated in 2010

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

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

Strategic elements for the next two years

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

Portfolio Plan

These protocols are in preparation by the group:

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

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

Collaboration with/participation in other groups

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

Personal note

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

Project Group Leukemia

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

Objectives

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

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

Activities

Trials activated in 2010

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

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

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

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

Strategic elements for the next two years

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

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

Portfolio Plan

These protocols are in preparation by the group:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Collaboration with / participation in other groups

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

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

Project Group Lung Cancer


1


2

Presidents:

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

Objectives

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

Activities

Activated trials in 2010

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

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

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

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

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

Strategic elements for the next two years

To complete our portfolio of studies by

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

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

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

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

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

Collaborations with / participation in other groups:

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

Project Group Lymphoma

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

Objectives

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

Activities

Trials Activated in 2010

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

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

Strategic elements for the next two years

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

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

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

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

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

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

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

Portfolio Plan

These protocols are in preparation by the group:

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

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

Collaboration with/participation in other groups

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

Project Group New Anticancer Drugs/ Phase I Trials

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

Objectives

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

Activities

Trials Activated in 2010

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

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

Collaboration with / participation in other groups

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

Project Group Urogenital Tumors


1


2

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

Objectives

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

Activities

Trials Activated in 2010

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

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

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

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

Strategic elements for the next two years

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

Portfolio Plan

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

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

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

Collaboration with / participation in other groups

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

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

Section Pathology

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

Short Introduction

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

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

Activities 2010

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

Outlook

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

Section Radio-Oncology

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

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

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

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

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

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

Network for Cancer Predisposition Testing and Counseling (CPTC)


1

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

Objectives of the Network

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

Activities 2010 and Outlook

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

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

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

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

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

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

Network for Outcomes Research


1


2

President:

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

Vice-President:

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

Network Activities in 2010 and Outlook

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

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

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

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

Two literature-based HEA were published:

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

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

Networking activities

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

Trials involving a health economic analysis

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

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

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

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

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

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

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

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

Collaboration with/participation in other groups

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

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

SAKK and Collaborating Groups

Lung Cancers

IALT Arriagada R, Dunant A, Pignon JP, Bergman B, Chabowski M, Grunenwald D, Kozlowski M, Le Péchoux C, Pirker R, Pinel MI, Tarayre M, Le Chevalier T. *Long-term results of the international adjuvant lung cancer trial evaluating adjuvant Cisplatin-based chemotherapy in resected lung cancer.* J Clin Oncol. 2010 Jan 1;28(1):35-42.

Breast Cancer

SAKK 24/06 Rochlitz C, Ruhstaller T, Lerch S, Spirig C, Huober J, Suter T, Bühlmann M, Fehr M, Schönenberger A, von Moos R, Winterhalder R, Rauch D, Müller A, Mannhart-Harms M, Herrmann R, Cliffe B, Mayer M, Zaman K; *on behalf of the Swiss Group for Clinical Cancer Research (SAKK). Combination of bevacizumab and 2-weekly pegylated liposomal doxorubicin as first-line therapy for locally recurrent or metastatic breast cancer. A multicenter, single-arm phase II trial (SAKK 24/06).* Ann Oncol. 2010 Jul 1. [Epub ahead of print]

ESO-MBC Pagani O, Senkus E, Wood W, Colleoni M, Cufer T, Kyriakides S, Costa A, Winer EP, Cardoso F; *on behalf of the ESO–MBC Task Force. International Guidelines for Management of Metastatic Breast Cancer: Can Metastatic Breast Cancer Be Cured?* J Natl Cancer Inst. 2010 Mar 10. [Epub ahead of print]

BIG 1-98 Phillips KA, Aldridge J, Ribi K, Sun Z, Thompson A, Harvey V, Thürlimann B, Cardoso F, Pagani O, Coates AS, Goldhirsch A, Price KN, Gelber RD, Bernhard J. *Cognitive function in postmenopausal breast cancer patients one year after completing adjuvant endocrine therapy with letrozole and/or tamoxifen in the BIG 1-98 trial.* Breast Cancer Res Treat. 2010 Nov 3. [Epub ahead of print].

Antonov J, Popovici V, Delorenzi M, Wirapati P, Baltzer A, Oberli A, Thurlimann B, Giobbie-Hurder A, Viale G, Altermatt HJ, Aebi S, Jaggi R. *Molecular risk assessment of BIG 1-98 participants by expression profiling using RNA from archival tissue.* BMC Cancer. 2010 Feb 9;10(1):37. [Epub ahead of print]

IBCSG 11-93 Paridaens RJ, Gelber S, Cole BF, Gelber RD, Thürlimann B, Price KN, Holmberg SB, Crivellari D, Coates AS, Goldhirsch A. *Adjuvant!((c)) Online estimation of chemotherapy effectiveness when added to ovarian function suppression plus tamoxifen for premenopausal women with estrogen-receptor-positive breast cancer.* Breast Cancer Res Treat. 2010 Feb 27. [Epub ahead of print]

Early Breast Cancer Trialists' Collaborative Group (EBCTCG), Correa C, McGale P, Taylor C, Wang Y, Clarke M, Davies C, Peto R, Bijker N, Solin L, Darby S. *Overview of the randomized trials of radiotherapy in ductal carcinoma in situ of the breast.* J Natl Cancer Inst Monogr. 2010(41):162-77.

Leukemia

SAKK 33/99 Passweg JR, Giagounidis AA, Simcock M, Aul C, Dobbelstein C, Stadler M, Ossenkoppele G, Hofmann WK, Schilling K, Tichelli A, Ganser A. *Immunosuppressive Therapy for Patients With Myelodysplastic Syndrome: A Prospective Randomized Multicenter Phase III Trial Comparing Antithymocyte Globulin Plus Cyclosporine With Best Supportive Care-SAKK 33/99.* J Clin Oncol. 2011 Jan 20;29(3):303-9. Epub 2010 Dec 13.

SAKK 34/02 Leupin N, Schuller JC, Solenthaler M, Heim D, Rovo A, Beretta K, Gregor M, Bargetzi MJ, Brauchli P, Himmelmann A, Hanselmann S, Zenhäusern R. *Efficacy of rituximab and cladribine in patients with chronic lymphocytic leukemia and feasibility of stem cell mobilization: a prospective multicenter phase II trial (protocol SAKK 34/02).* Leuk Lymphoma. 2010 51:613-619

APL Ades L, Guerci A, Raffoux E, Sanz M, Chevallier P, Lapusan S, Recher C, Thomas X, Rayon C, Castaigne S, Tournilhac O, de Botton S, Ifrah N, Cahn J. Y, Solary E, Gardin C, Fegueux N, Bordessoule D, Ferrant A, Meyer-Monard S, Vey N, Dombret H, Degos L, Chevret S, and Fenaux P, 2009, *Very long-term outcome of acute promyelocytic leukemia after treatment wtih all trans retinoic acid and chemotherapy: the European APL Group experience.* Blood. 2010 Mar 4;115(9):1690-6.

GRAALL-2003 Maury S, Huguet F, Leguay T, Lacombe F, Maynadie M, Girard S, de Labarthe A, Kuhlein E, Raffoux E, Thomas X, Chevallier P, Buzyn A, Delannoy A, Chalandon Y, Vernant J. P, Rousselot P, Macintyre E, Ifrah N, Dombret H, and Bene M. C, 2009, *Adverse prognostic significance of CD20 expression in adults with Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia.* Haematologica. 2010 Feb;95(2):324-8.

HOVON Lugthart S, Gröschel S, Beverloo HB, Kayser S, Valk PJ, van Zelderen-Bhola SL, Ossenkoppele GJ, Vellenga E, Eva VD, Schanz U, Verhoef G, Vandenberghe P, Ferrant A, Köhne CH, Pfreundschuh M, Horst HA, Koller E, von Lilienfeld-Toal M, Bentz M, Ganser A, Schlegelberger B, Jotterand M, Krauter J, Pabst T, Theobald M, Schlenk RF, Delwel R, Döhner K, Löwenberg B, Döhner H. Clinical, *Molecular, and Prognostic Significance of WHO Type inv(3)(q21q26.2)/t(3;3)(q21;q26.2) and Various Other 3q Abnormalities in Acute Myeloid Leukemia.* J Clin Oncol. 2010 28:3890-3898

HOVON-43 Löwenberg B, Beck J, Graux C, van Putten W, Schouten HC, Verdonck LF, Ferrant A, Sonneveld P, Jongen-Lavrencic M, von Lilienfeld-Toal M, Biemond BJ, Vellenga E, Breems D, de Muijnck H, Schaafsma MR, Verhoef G, Döhner H, Gratwohl A, Pabst T, Ossenkoppele GJ, Maertens J. *Gemtuzumab ozogamicin as postremission treatment in AML at 60 years of age or more: results of a multicenter phase III study.* Blood. 2010 Apr 1;115(13): 2586-91. Epub 2010 Jan 26.

CML IV Saussele S, Lauseker M, Gratwohl A, Beelen D, Bunjes D, Schwerdtfeger R, Kolb HJ, Ho A, Falge C, Holler E, Schlimok G, Zander A, Arnold R, Kanz L, Dengler R, Haferlach C, Schlegelberger B, Pfirrmann M, Müller M, Schnittger S, Leitner A, Pletsch N, Hochhaus A, Hasford J and Hehlmann R, for the German CML Study Group. *Allogeneic hematopoietic stem cell transplantation (allo SCT) for chronic myeloid leukemia in the imatinib era: evaluation of its impact within a subgroup of the randomized German CML Study IV.* Blood. 2010;115:1880-1885

ALL Talamo A, Chalandon Y, Marazzi A and Jotterand M Clonal. *Heterogeneity and chromosomal instability in high hyperdiploid acute lymphoblastic leukemia.* Cancer Genetics and Cytogenetics 2010;203:209-214.

Lymphoma

SAKK 35/98 Martinelli G, Hsu Schmitz SF, Utiger U, Cerny T, Hess U, Bassi S, Okkinga E, Stupp R, Stahel R, Heizmann M, Vorobiof D, Lohri A, Dietrich PY, Zucca E, Ghielmini M. *Long-Term Follow-Up of Patients With Follicular Lymphoma Receiving Single-Agent Rituximab at Two Different Schedules in Trial SAKK 35/98.* J Clin Oncol. 2010 Aug 9. [Epub ahead of print]

HD-10 Engert A, Plütschow A, Eich HT, Lohri A, Dörken B, Borchmann P, Berger B, Greil R, Willborn KC, Wilhelm M, Debus J, Eble MJ, Sökler M, Ho A, Rank A, Ganser A, Trümper L, Bokemeyer C, Kirchner H, Schubert J, Král Z, Fuchs M, Müller-Hermelink HK, Müller RP, Diehl V. *Reduced treatment intensity in patients with early-stage Hodgkin's lymphoma.* N Engl J Med. 2010 Aug 12;363(7):640-52.

HD-11 Eich HT, Diehl V, Görgen H, Pabst T, Markova J, Debus J, Ho A, Dörken B, Rank A, Grosu AL, Wiegel T, Karstens JH, Greil R, Willich N, Schmidberger H, Döhner H, Borchmann P, Müller-Hermelink HK, Müller RP, Engert A. *Intensified Chemotherapy and Dose-Reduced Involved-Field Radiotherapy in Patients With Early Unfavorable Hodgkin's Lymphoma: Final Analysis of the German Hodgkin Study Group HD11 Trial.* J Clin Oncol. 2010 Sep 20;28(27):4199-206. Epub 2010 Aug 16.

HD-15/EPO Engert A, Josting A, Haverkamp H, Villalobos M, Lohri A, Sökler M, Zijlstra J, Sturm I, Topp MS, Rank A, Zenz T, Vogelhuber M, Nogova L, Borchmann P, Fuchs M, Flechtner HH, Diehl V. *Epoetin alfa in patients with advanced-stage Hodgkin's lymphoma: results of the randomized placebo-controlled GHSG HD15EPO trial.* J Clin Oncol. 2010 May 1;28(13):2239-45. Epub 2010 Apr 5.

IFM 2005-01 Moreau P, Attal M, Pégourié B, Planche L, Hulin C, Facon T, Stoppa AM, Fuzibet JG, Grosbois B, Doyen C, Ketterer N, Sebban C, Kolb B, Chaleteix C, Dib M, Voillat L, Fontan J, Garderet L, Jaubert J, Mathiot C, Esseltine D, Avet-Loiseau H, Harousseau JL. *Achievement of VGPR to induction therapy is an important prognostic factor for longer PFS in the IFM 2005-01 trial.* Blood. 2010 Nov 23. [Epub ahead of print]
Harousseau JL, Attal M, Avet-Loiseau H, Marit G, Caillot D, Mohty M, Lenain P, Hulin C, Facon T, Casassus P, Michallet M, Maisonneuve H, Benboubker L, Maloisel F, Petillon MO, Webb I, Mathiot C, Moreau P. *Bortezomib Plus Dexamethasone Is Superior to Vincristine Plus Doxorubicin Plus Dexamethasone As Induction Treatment Prior to Autologous Stem-Cell Transplantation in Newly Diagnosed Multiple Myeloma: Results of the IFM 2005-01 Phase III Trial.* J Clin Oncol. 2010 Sep 7. [Epub ahead of print]
Moreau P, Hulin C, Marit G, Caillot D, Facon T, Lenain P, Berthou C, Pégourié B, Stoppa AM, Casassus P, Michallet M, Benboubker L, Maisonneuve H, Doyen C, Leyvraz S, Mathiot C, Avet-Loiseau H, Attal M, Harousseau JL. *Stem cell collection in patients with de novo multiple myeloma treated with the combination of bortezomib and dexamethasone before autologous stem cell transplantation according to IFM 2005-01 trial.* Leukemia. 2010 Jun;24(6):1233-5. Epub 2010 Apr 29.

IFM-90/IFM-04/IFM-9902/IFM-9904 Barlogie B, Attal M, Crowley J, van Rhee F, Szymonifka J, Moreau P, Durie BG, Harousseau JL. *Long-Term Follow-Up of Autotransplantation Trials for Multiple Myeloma: Update of Protocols Conducted by the Intergroupe Francophone du Myelome, Southwest Oncology Group, and University of Arkansas for Medical Sciences.* J Clin Oncol. 2010 Mar 1;28(7):1209-14. Epub 2010 Jan 19.

RICOVER-60 Ott G, Ziepert M, Klapper W, Horn H, Szczepanowski M, Bernd HW, Thorns C, Feller AC, Lenze D, Hummel M, Stein H, Müller-Hermelink HK, Frank M, Hansmann ML, Barth TF, Möller P, Cogliatti S, Pfreundschuh M, Schmitz N, Trümper L, Loeffler M, Rosenwald A. *Immunoblastic morphology but not the immunohistochemical GCB/non-GCB classifier predicts outcome in diffuse large B-cell lymphoma in the RICOVER-60 trial of the DSHNHL.* Blood. 2010 Aug 24. [Epub ahead of print]

Gastrointestinal Cancers

SAKK 41/03 von Moos R, Roth A, Ruhstaller T, Widmer L, Uhlmann C, Cathomas R, Köberle D, Simcock M, Lanz D, Popescu R. *Oxaliplatin, irinotecan and capecitabine (OCX) for first-line treatment of advanced/metastatic colorectal cancer: a phase I trial (SAKK 41/03).* Onkologie. 2010;33(6):295-9. Epub 2010 May 14.

SAKK 43/99 Biffi R, Fazio N, Luca F, Chiappa A, Andreoni B, Zampino MG, Roth A, Schuller JC, Fiori G, Orsi F, Bonomo G, Crosta C, Huber O. *Surgical outcome after docetaxel-based neoadjuvant chemotherapy in locally-advanced gastric cancer.* World J Gastroenterol. 2010 Feb 21;16(7):868-74.

SAKK 44/00 Bernhard J, Dietrich D, Glimelius B, Hess V, Bodoky G, Scheithauer W, Herrmann R. *Estimating prognosis and palliation based on tumour marker CA 19-9 and quality of life indicators in patients with advanced pancreatic cancer receiving chemotherapy.* Br J Cancer. 2010 Sep 28. [Epub ahead of print]

SAKK 60/00 PETACC-3 EORTC 40993 Roth A. D, Tejpar S, Delorenzi M, Yan P, Fiocca R, Klingbiel D, Dietrich D, Biesmans B, Bodoky G, Barone C, Aranda E, Nordlinger B, Cisar L, Labianca R, Cunningham D, Van Cutsem E, and Bosman F, 2009, *Prognostic Role of KRAS and BRAF in Stage II and III Resected Colon Cancer: Results of the Translational Study on the PETACC-3, EORTC 40993, SAKK 60-00 Trial.* J Clin Oncol. 2010 Jan 20;28(3).

SAKK 75/02 Jost C, Binek J, Schuller JC, Bauerfeind P, Metzger U, Werth B, Knuchel J, Frossard JL, Bertschinger P, Brauchli P, Meyenberger C, Ruhstaller T. *Endosonographic radial tumor thickness after neoadjuvant chemoradiation therapy to predict response and survival in patients with locally advanced esophageal cancer: a prospective multicenter phase ll study by the Swiss Group for Clinical Cancer Research (SAKK 75/02).* Gastrointest Endosc. 2010 Jun;71(7):1114-1121. Epub 2010 Mar 20.

SAKK 76/02 Ruhstaller T, Templeton A, Ribi K, Schuller JC, Borner M, Thierstein S, von Moos R, Pederiva S, Lohri A, Lombriser N, von Briel C, Koeberle D, Popescu R. *Intense therapy in patients with locally advanced esophageal cancer beyond hope for surgical cure: a prospective, multicenter phase II trial of the Swiss Group for Clinical Cancer Research (SAKK 76/02).* Onkologie. 2010;33(5):222-8. Epub 2010 Apr 9.

SAKK 77/06 Koeberle D, Montemurro M, Samaras P, Majno P, Simcock M, Limacher A, Lerch S, Kovàcs K, Inauen R, Hess V, Saletti P, Borner M, Roth A, Bodoky G. *Continuous Sunitinib Treatment in Patients with Advanced Hepatocellular Carcinoma: A Swiss Group for Clinical Cancer Research (SAKK) and Swiss Association for the Study of the Liver (SASL) Multicenter Phase II Trial (SAKK 77/06).* Oncologist. 2010 Mar 4. [Epub ahead of print]

Sarcoma

Euro-EWING 99 Ladenstein R, Pötschger U, Le Deley MC, Whelan J, Paulussen M, Oberlin O, van den Berg H, Dirksen U, Hjorth L, Michon J, Lewis I, Craft A, Jürgens H. *Primary Disseminated Multifocal Ewing Sarcoma: Results of the Euro-EWING 99 Trial.* J Clin Oncol. 2010 Jun 14. [Epub ahead of print]

New Drugs

SKSD00701 Gallerani E, Bauer J, Hess D, Boehm S, Droege C, Jeckelmann S, Miani M, Herrmann R, Marsoni S, Sperka S, Sessa C. *A phase I study of the oral platinum agent satraplatin in sequential combination with capecitabine in the treatment of patients with advanced solid malignancies.* Acta Oncol. 2010 Dec 27. [Epub ahead of print]

Outcomes Research

Joerger M, Matter-Walstra K, Früh M, Kühnel U, Szucs T, Pestalozzi B, Schwenkglenks M. *Addition of cetuximab to first-line chemotherapy in patients with advanced non-small-cell lung cancer: a cost-utility analysis.* Ann Oncol. 2010 Sep 13. [Epub ahead of print]

Matter-Walstra KW, Dedes KJ, Schwenkglenks M, Brauchli P, Szucs TD, Pestalozzi BC. *Trastuzumab beyond progression: a cost-utility analysis.* Ann Oncol. 2010 May 5. [Epub ahead of print]

Other SAKK

Brauchli P, Thürlimann B, Crowe SN, Herrmann R. *What Is the Value of the 21-Gene Recurrence Score?* J Clin Oncol. 2010 Aug 30. [Epub ahead of print]

Ess S, Savidan A, Frick H, Rageth C, Vlastos G, Lütolf U, Thürlimann B. *Geographic variation in breast cancer care in Switzerland.* Cancer Epidemiol. 2010 Feb 23. [Epub ahead of print]

Farese SA, Aebi S. *Infiltrating Lobular Carcinoma of the Breast: Systemic Treatment.* Breast Dis. 2009 Oct 21;30: 45-52. [Epub ahead of print]

Resoconto annuale dal 1° gennaio al 31 dicembre (in CHF)	**2010**	**2009**
Reddito di esercizio		
Contributi per la ricerca SBF[1]	4 109 180.00	4 019 850.00
Altri contributi per la ricerca[2]	1 225 200.00	803 600.00
Contributi per la ricerca santésuisse	1 278 960.00	717 062.00
Ricavi collaborazioni industriali	3 214 106.00	4 126 604.45
Ricavi gruppi di studio esteri	201 234.07	89 910.11
Redditi bollettino sul cancro	364 248.00	326 490.00
Donazione, Legati & Eredità	165 211.95	57 569.80
Redditi vari	446 600.61	287 745.52
Totale reddito di esercizio	**11 004 740.63**	**10 428 831.88**
Spese di esercizio		
Costi per studi vari	– 1 381 063.85	– 824 010.07
Contributi per la ricerca IBCSG[3]	– 250 000.00	– 250 000.00
Contributi per la ricerca Centri	– 2 877 736.46	– 3 009 964.17
Costi di trasferta e viaggi di rappresentanza	– 201 215.30	– 167 700.44
Altre spese di esercizio	– 135 061.63	– 192 479.10
Totale spese di esercizio	**– 4 845 077.24**	**– 4 444 153.78**
Subtotale 1	6 159 663.39	5 984 678.10
Costi di coordinamento		
Costi per il personale	– 5 805 948.34	– 5 016 747.44
Altri costi di coordinamento	– 1 132 768.56	– 1 042 005.77
Totale costi di coordinamento	**– 6 938 716.90**	**– 6 058 753.21**
Subtotale 2	– 779 053.51	– 74 075.11
Risultato finanziario		
Reddito finanziario	42 433.03	18 536.98
Oneri finanziari	– 60 624.07	– 4 695.73
Totale risultato finanziario	**– 18 191.04**	**13 841.25**
Subtotale 3	– 797 244.55	– 60 233.86
Variazione fondi		
Scioglimento e accantonamenti	210.00	3 133.00
Scioglimento Fondi	38 510.00	30 568.00
Totale variazione fondi	**38 720.00**	**33 701.00**
Subtotale 4	– 758 524.55	– 26 532.86
Attività al di fuori del periodo		
Attività al di fuori del periodo considerato	11 568.78	19 736.66
Scioglimento di accantonamenti non necessari	– 638.85	– 126 850.80
Totale attività al di fuori del periodo considerato	**10 929.93**	**– 107 114.14**
Risultato complessivo	**– 747 594.62**	**– 133 647.00**

1 Segreteria di stato per l'educazione e la ricerca SER

2 Lega contro il cancro / Ricerca svizzera contro il cancro / Fondazione svizzera per la ricerca clinica contro il cancro

3 International Breast Cancer Study Group IBCSG

SAKK Pool Industrie 2010

Ringraziamo i gruppi farmaceutici per il loro sostegno:

Amgen Switzerland AG
AstraZeneca AG
Baxter AG
Bayer Schering Pharma (Schweiz) AG
Boehringer Ingelheim AG
Bristol-Myers Squibb GmbH
Celgene GmbH
EBEWE Pharma Schweiz AG
Eisai Pharma AG
Eli Lilly Suisse S.A.
Essex Chemie AG
Genzyme GmbH
GlaxoSmithKline AG
Janssen-Cilag AG
Lipomed AG
Mepha Pharma AG
Merck (Schweiz) AG
Mundipharma Medical Company
Novartis Pharma Schweiz AG
Pfizer AG
PharmaMar S.A.U.
Robapharm AG
Roche Pharma (Schweiz) AG
sanofi-aventis (suisse) sa
Takeda Pharma AG
Vifor AG

Contributi pubblici e di terzi

Segreteria di Stato per l'educazione e la ricerca SER
Fondazione Svizzera per la Ricerca sul Cancro
Lega svizzera contro il cancro
Fondazione svizzera per la ricerca clinica contro il cancro
Donatori privati

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

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

Conto
Conto donatori SAKK:
CP 60-2954422-0

Redazione
Claudia Herren, Nicole Corminboeuf
Realizzazione
atelierrichner.ch
Stampa
Länggass Druck AG, Bern

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