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

Rapporto annuale

09

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http://sakk.ch

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Attualità 2009

Prof. Dott. Richard Herrmann | Presidente del SAKK

Questa relazione di esercizio fornisce il rendiconto delle attività del SAKK per il 2009. Le performance descritte sono, ancora una volta, significative. Vorrei sottolineare, in particolare, che oltre ai compiti propri del SAKK, è stato fatto molto per il miglioramento della funzionalità dell' organizzazione. Il numero del personale è stato aumentato, soprattutto per professionalizzare le varie relazioni esterne. Il SAKK ha anche reso più trasparenti, grazie a nuovi regolamenti, i processi interni. Questi sviluppi hanno contribuito a far sì che il SAKK sia riconosciuto come organizzazione competente per la ricerca clinica non solo in Svizzera, ma anche nel resto d'Europa. Per quanto i risultati raggiunti sono di tutto rispetto, non vi è tempo per cullarsi sugli allori. Esistono ancora molte sfide da affrontare in vari campi.

Auspichiamo avere con le autorità (Swissmedic, UFSP) e le diverse commissioni etiche, una collaborazione improntata sulla fiducia, cosi' da portare a termine in modo corretto i compiti regolamentati da leggi e ordinanze. Ci attendiamo inoltre che queste organizzazioni sostengano il nostro lavoro e contribuiscano a promuovere la ricerca clinica in Svizzera – come, del resto, è anche stabilito dalla legge – e non ad ostacolarla. Troppo spesso ci si ritrova nella posizione di dover chiedere e questo ci distrae dal nostro obiettivo principale che è quello di portare giovamento agli ammalati di cancro. A mio avviso, servono posizioni chiare, che vanno sostenute anche di fronte all'opinione pubblica, e permettano di accordarsi con altri enti svizzeri attivi nella ricerca clinica.

Le sfide per l'ideazione di nuovi studi è di tutt'altra natura. I risultati della ricerca biomolecolare influiscono sempre di più sulla nostra attività clinica quotidiana. Oggi non esiste più il carcinoma mammario o il carcinoma bronchiale. Le subclassificazioni portano a strategie terapeutiche differenziate. Per la ricerca clinica questo significa che, nell'ambito di uno studio, per molte malattie analizziamo solamente una subentità, e quindi possiamo reclutare solamente un numero ristretto di pazienti. Per raggiungere ogni anno il numero di pazienti desiderato è necessario attivare più studi. Questa situazione che ci costringe ad allargare la cooperazione internazionale, perchè lavorando nella sola Svizzera, per molte indicazioni non siamo più in grado di ottenere risultati validi. E' necessario inoltre riflettere in quali altri campi dell'oncologia esista la possibilità di fare ricerca. Lo studio 41/06 relativo alla terapia di mantenimento a base di Bevacizumab per il trattamento del carcinoma colorettale ne è un esempio. Altre questioni sorgono relativamente agli strumenti diagnostici, ad esempio nella cura post-terapia, ma anche negli ambiti della radiooncologia e nei trattamenti operativi. Fortunatamente molte colleghe e colleghi oltre a svolgere il loro lavoro con competenza ed entusiasmo, hanno anche il coraggio di affrontare sfide difficili.

Negli ultimi anni il Centro di coordinamento SAKK di Berna si è sviluppato fino a diventare un centro di competenza per l'organizzazione nazionale e internazionale di studi clinici. Vedo in prima persona l'impegno che collaboratrici e collaboratori profondono nel loro lavoro e noto anche lo sviluppo positivo che ha avuto l'interazione fra Centro di coordinamento e membri del SAKK negli ospedali. Colgo l'occasione per ringraziare in questa sede coloro i quali con dedizione hanno svolto il loro lavoro. Un ringraziamento particolare vorrei rivolgerlo al Direttore del SAKK Dott. Peter Brauchli e ai suoi collaboratori.

Tutto il lavoro del SAKK non sarebbe possibile senza i contributi finanziari che arrivano prevalentemente dalla confederazione attraverso la Segreteria di Stato per l'educazione e la ricerca (SER). Altri fondi provengono dalla cooperazione con l'industria, dalla Lega svizzera contro il cancro, dalla Ricerca svizzera contro il cancro, dalla Fondazione Svizzera per la ricerca clinica sul cancro (SSKK) e da donazioni di privati. Per tutti questi aiuti vi siamo infinitamente grati.

Gruppo Svizzero di Ricerca Clinica sul Cancro SAKK

Attività del centro di coordinamento

Dott. Peter Brauchli | Direttore del SAKK

Perchè è nato il SAKK?

Il Gruppo Svizzero di Ricerca Clinica sul Cancro (SAKK) è un gruppo di collaborazione operante a livello nazionale. La sua missione è quella di sviluppare ulteriormente le terapie anticancro esistenti e di studiare l'efficacia e la tollerabilità di nuove terapie. I risultati devono andare quanto prima a beneficio dei pazienti. Dalla Segreteria di Stato per l'educazione e la ricerca (SER) il SAKK, insieme al Gruppo Oncologia Pediatrica Svizzera (SPOG), sono stati incaricati di effettuare ricerca clinica nel campo dell'oncologia. Il Centro di coordinamento del SAKK sostiene i ricercatori nello sviluppo, nell'attuazione e nella valutazione degli studi oncologici, vagliandone tutte le possibilità quali la chirurgia, la radioterapia e le terapie sistemiche. Grazie a questo sostegno è possibile, in qualità di membri del SAKK, fare ricerca in cinque cliniche universitarie e in altri 12 ospedali.

Nel 2009 abbiamo fatto importanti progressi che ci consentono di lavorare in modo più efficiente e di raggiungere i nostri obiettivi.

Regolamento organizzativo per il Comitato direttivo

Il regolamento organizzativo è stato approvato in giugno dall'assemblea dei membri e riconosciuto valido dal SER. Il Comitato direttivo del SAKK lavora secondo i principi della corporate governance delle Non Profit Organization (NPO) ed è responsabile per la scelta degli studi in base a criteri riconosciuti validi a livello internazionale. Nel regolamento è chiaramente stabilito sulla base di quali criteri e documenti il Comitato decide in merito alle proposte di studio. Eventuali conflitti di interesse vanno ovviamente dichiarati. Il regolamento sancisce, inoltre, l'obbligo di applicazione del principio del doppio controllo – iniziale e finale – in merito alle varie proposte di studio.

Regolamento dei gruppi di progetto

Questo regolamento è stato approvato in novembre dall'assemblea dei membri. Esso fissa i criteri di appartenenza ai gruppi di progetto e concretizza il diritto dei gruppi di progetto di presentare proposte di studio all'attenzione del Comitato. Il regolamento prevede anche la partecipazione di un esperto internazionale alle riunioni dei gruppi di progetto.

Entrambi i regolamenti sono fondamentali per una collaborazione efficiente fra i gruppi di progetto e il Comitato direttivo. Si garantisce cosi' l'indipendenza dei vari organi; la trasparenza delle procedure viene mantenuta e si sviluppano progetti maturati attraverso un processo iterativo.

Affinché queste procedure possano funzionare in modo ottimale è indispensabile il sostegno del centro di Coordinamento. Il dipartimento di coordinamento degli studi è stato ulteriormente ampliato per portare avanti futuri progetti in maniera più efficiente. È stata anche creata una Commissione per l'esame delle proposte, specifica per ogni singolo progetto. Essa dovrà seguire fin dai primi stadi il processo di esame dei progetti di studio.

Strategia

La Commissione scientifica del SAKK è composta da sei esperti stranieri indipendenti. Nel febbraio del 2009 la Commissione, il Comitato Direttivo del SAKK, i presidenti dei gruppi di progetto del SAKK e i rappresentanti del Centro di coordinamento del SAKK si sono riuniti per la seconda volta per discutere sulla strategia da applicare e sul posizionamento da raggiungere. Durante la riunione

dell'ottobre 2009 il Comitato direttivo ha ulteriormente sviluppato le sue raccomandazioni e ha fissato gli obiettivi a lungo termine.

Obiettivi dichiarati sono il reclutamento di un maggior numero di pazienti nei vari studi e il rafforzamento della leadership del SAKK negli studi eseguiti a livello internazionale. I membri del Comitato direttivo, inoltre, hanno stabilito le priorità, gli obiettivi e i requisiti che i gruppi di studio del SAKK devono soddisfare.

Durante la riunione si è anche stabilito che per le indicazioni più importanti i ricercatori devono essere incoraggiati a condurre più studi di fase III, e considerare anche la ricerca traslazionale, la ricerca dei risultati, il rapporto costi/benefici, la qualità di vita del paziente e il trattamento post-terapia.

Allo scopo di sfruttare adeguatamente la crescente produttività del nostro network, dovranno essere stabiliti ulteriori obiettivi.

Il Comitato direttivo ha accolto alcuni suggerimenti della Commissione scientifica e ha fissato per i prossimi anni i seguenti obiettivi:
- Istituzione del tumor board (Comitato per la valutazione dei tumori) presso i centri affiliati;
- Creazione di condizioni quadro in grado di stimolare anche gli oncologi privati a partecipare agli studi SAKK;
- Estensione dell'attività di studio ad altri tipi di cancro, quali ad esempio i tumori alla testa e nella zona del collo, i tumori del sistema nervoso centrale, i tumori ginecologici, i sarcomi, i melanomi e i tumori al pancreas;
- Specializzazione in malattie rare;
- Promozione e allargamento della collaborazione con Santésuisse;
- Miglioramento della collaborazione internazionale con Paesi piccoli (paesi nordici, Paesi Bassi, Belgio, Austria, Polonia, Centri ungheresi o gruppi)
- Semplificazione delle procedure di approvazione da parte delle commissioni etiche e di Swissmedic;
- Sostegno dei piccoli centri attraverso un «flying data manager».

All'assembea semestrale di novembre, durante la riunione del Comitato direttivo con i presidenti dei gruppi di progetto e con il Centro di coordinamento sono state comunicati i requisiti dei gruppi di progetto e le direttive strategiche. Il passo successivo è stato quello di far confluire queste idee in una richiesta di sostegno federale per il prossimo periodo di quattro anni, inviata poi all'attenzione del SER.

Attività di studio

L'anno scorso il SAKK ha incluso 831 pazienti in 41 studi clinici. Questo è il numero più alto raggiunto negli ultimi dieci anni. Di questi pazienti, 481 sono stati reclutati per studi propri del SAKK. Il Comitato direttivo ha accettato, in totale, 11 studi SAKK. Nel 2009 il SAKK ha sviluppato 16 nuovi studi, sei dei quali sono già stati iniziati. L'anno scorso sotto responsabilità SAKK o per i quali la sua partecipazione è stata determinante sono stati pubblicati 15 manoscritti.

Nella maggior parte degli studi il reclutamento dei pazienti è stato alquanto soddisfacente. Gli studi di fase II a reclutamento rapido sono diventati, nel frattempo, però una sfida particolare. L'esperienza dimostra che il reclutamento di pazienti per gli studi di fase II avviene in modo più rapido del previsto. Molti centri hanno grande interesse a parteciparvi. Ma un reclutamento eccessivamente rapido di pazienti è spesso in conflitto con l'analisi intermedia programmata. Inoltre, i centri che aprono lo studio relativamente tardi, hanno poco tempo per includere pazienti.

Nel 2009 è stato iniziato il primo studio nel quale le informazioni sono state completamente raccolte dal nostro sistema elettronico di rilevamento dati SINATRAS. Questo sistema informatico di raccolta dati viene continuamente sviluppato.

Esso permette di ridurre notevolmente la mole di lavoro in caso di richiesta di dati da parte dei medici al Centro di coordinamento e ai vari altri centri.

La richiesta di autorizzazione per lo studio SAKK 08/08 è avvenuta secondo il nuovo concetto della Commissione etica agevolata. Questo concetto é stato promosso quest'anno dalle commissioni etiche cantonali (AGEK). Il SAKK potrà maturare in questo senso ulteriori esperienze fino alla fine del 2010.

Corsi di aggiornamento
Nel 2009 il SAKK ha tenuto corsi di aggiornamento per medici sperimentatori e ha organizzato, insieme alla Clinical Trial Unit (CTU) di Berna, un ulteriore corso di perfezionamento per i responsabili degli studi. Il dipartimento statistico del SAKK, assieme all'Istituto di Biostatistica dell'Università di Zurigo, ha tenuto un simposio SAKK dal titolo «Stopping trials early – good for patients or for sponsors?». Tutte le manifestazioni sono state accolte con grande interesse e hanno visto la partecipazione di vari e numerosi gruppi professionali.

Cooperazione
Nel settore della ricerca clinica, sempre in rapida evoluzione, è indispensabile che in Svizzera, il SAKK si posizioni chiaramente e sostenga i propri interessi. Per questo si cerca di collaborare sempre di più con altri gruppi, così che si possano portare le nostre istanze a livello politico e sensibilizzare fasce sempre più ampie dell'opinione pubblica verso la ricerca clinica.

In un primo incontro con alcuni rappresentanti della Swiss Clincal Trial Organisation (SCTO) si è stabilito che la collaborazione operativa già esistente deve essere portata avanti e, ove occorra, addirittura ampliata.

Oncosuisse
Nell'estate del 2009 Oncosuisse è stata trasformata in una società semplice, che si concentra ancora di più sulle questioni politico-strategiche nel campo della lotta contro il cancro. Oncosuisse è finanziata con contributi dei quattro soci Ricerca svizzera sul cancro, Lega svizzera contro il cancro, SAKK e SPOG. La presidenza di Oncosuisse è detenuta dal Presidente del SAKK Prof. Dott. Richard Hermann. La direzione amministrativa è affidata al direttore del SAKK Dott. Peter Brauchli. Grazie a questa unione di cariche si creano utili sinergie.

Il progetto centrale di Oncosuisse consiste nella messa a punto del nuovo Programma Nazionale per la lotta contro il cancro (NKP) per il quinquennio 2011–2015. Il programma NKP è uno strumento politico di coordinamento a livello nazionale che si prefigge di migliorare la ricerca, la prevenzione, la diagnosi precoce e il trattamento del cancro, nonché il superamento delle conseguenze della malattia. A questa nuova edizione il SAKK sta lavorando attivamente ed è responsabile del capitolo su Ricerca e Terapie.

Centro di coordinamento
L'anno è stato caratterizzato sia da assenze temporanee nelle funzioni dirigenziali (dimissioni e congedi maternità), sia dal numero ridotto dei progetti in generale, sia dalla ridotta disponibilità di personale e competenze.

Nel Centro di coordinamento del SAKK il dipartimento di coordinamento degli studi è stato ristrutturato e suddiviso in quattro gruppi. La novità è il dipartimento «Clinical Trial Management (CTM)» diretto da Ursula Kühnel. Questo provvedimento ha permesso di snellire le procedure e ha definito in modo più chiaro le responsabilità.

Per far fronte al crescente numero di studi da sviluppare e al lavoro che essi comportano, alla fine del 2009 è stato aumentato di nove unità il numero di collaboratori fissi del SAKK (per un totale di 4075 percentuale di posti di lavoro). Soprattutto per il campo di attività principale (sviluppo e realizzazione di studi) serviva ulteriore personale. Attualmente il responsabile del Team Monitoring è la Dott.ssa Céline Genton. Per il coordinamento degli studi è stato possibile arruolare due nuove responsabili di gruppo, la Dott.ssa Simona Berardi e Anja Grzesiczek, con già alle spalle un'esperienza nel settore della ricerca clinica. Oltre

al Dipartimento CTM, è stato ampliato anche quello di Informatica. Il Dott. Peter Durrer, subentrato a Doris Lanz, ha iniziato la sua attività quale responsabile della QA & GCP Compliance nel novembre del 2009. A causa della necessità di spazi più ampi i Dipartimenti Informatica, Partner Relations e Regulatory Affairs si sono trasferiti nei nuovi uffici alla Effingerstrasse 60.

L'impegno di tutti i collaboratori del centro di coordinamento è stato enorme anche se le condizioni non sono sempre state ideali,. Per questo lavoro indefesso al servizio del SAKK ringrazio di cuore tutti i responsabili dei vari Dipartimenti e i loro gruppi.

Membri del consiglio direttivo

Presidente
Prof. Richard Herrmann
Universitätsspital Basel

Vizepresidente
Prof. Beat Thürlimann
Kantonsspital St. Gallen

Prof. Daniel Betticher
Kantonsspital Freiburg

Prof. Stephan Bodis
Kantonsspital Aarau

PD Dr. Yves Chalandon
Hôpital Universitaire
de Genève

Prof. Martin Fey
Inselspital Bern

Prof. Michele Ghielmini
Ospedale Regionale
Lugano

Prof. Holger Moch
Universitätsspital Zürich

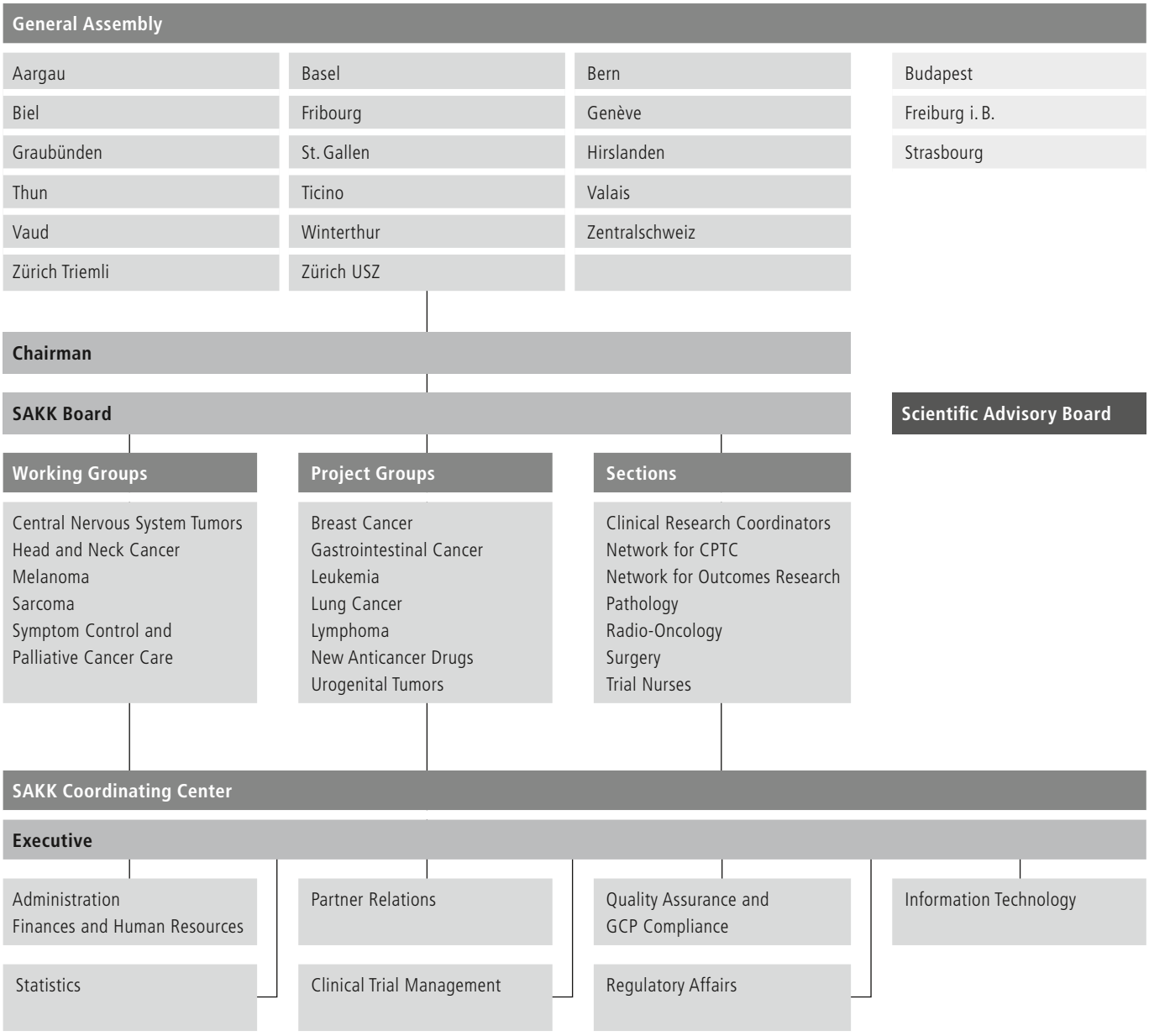
Prof. Christoph Renner
Universitätsspital Zürich

PD Dr. Arnaud Roth
Hôpital Cantonal
Universitaire Genève

Dott. Roger von Moos
Kantonsspital Chur

Prof. Walter Richard Marti
Universitätsspital Basel

Organigram Swiss Group for Clinical Cancer Research (SAKK)



Dirigenti, onorificenze e promozioni all'interno del SAKK

Primario
- Prof. Dott. Walter R. Marti, primario di Chirurgia, Ospedale cantonale di Aarau

Direzione medica
- Dott. Christoph Mamot, libero docente, dirigente medico di Oncologia, Ospedale cantonale di Aarau
- Dott. Ulrich Mey, libero docente, dirigente medico di Oncologia, Ospedale cantonale di Coira
- Prof. Dott. Bernhard Pestalozzi, dirigente medico, Clinica e Policlinico di Oncologia, Clinica universitaria di Zurigo

Libera docenza
- Dott. Frank Stenner-Liewen, libero docente, capo clinica della Clinica e del Policlinico di Oncologia, Clinica universitaria di Zurigo
- Dott. Florian Strasser, libero docente, capoclinica di Oncologia e Medicina palliativa, Ospedale cantonale di San Gallo

Cattedre
- Prof. Dott. Thomas Pabst, dirigente medico dell'Istituto di Medicina oncologica, Inselspital Berna
- Prof. Dott. Markus Manz, direttore della clinica di Ematologia, Clinica universitaria di Zurigo
- Prof. Dott. Ssa Cristiana Sessa, IOSI, Ospedale San Giovanni (Titular Professor)

Nomine
- Prof. Dott. Donal Hollywood, Head Academic Unit of Clinical and Molecular Oncology, Trinity College Dublino: Membro SAKK Advisory Board (succede al Prof. Dott. Michael Baumann)
- Prof. Dott. Christoph Renner, dirigente medico della Clinica e del Policlinico di Oncologia, Clinica universitaria di Zurigo: referente di Medicina interna
- Prof. Dott. Beat Thürlimann, primario Brustzentrum, Ospedale cantonale di San Gallo: Presidente SAKK dal 1° luglio 2010
- Dott. Emanuele Zucca, libero docente IOSI, Ospedale San Giovanni: Presidente SAKK Gruppo di progetto Linfoma (succede al Dott. Nicolas Ketterer, libero docente)

Riconoscimenti
- Prof. Dott. Alois Gratwohl, responsabile di Ematologia, Clinica universitaria di Basilea: Premio della Lega svizzera contro il cancro
- Dott. Ulrich Güller, libero docente, professore ass., Università di Basilea: Premio Pfizer per la ricerca in Oncologia 2009
- Dott. ssa Viviane Hess, libera docente, Clinica di Oncologia, Clinica universitaria di Basilea Premio Pfizer per la ricerca in Oncologia 2009 e Marie-Heim-Vögtlin Premio FNS
- Dott. Igor Langer, libero docente, primario di Chirurgia, Ospedale cantonale Bruderholz: Premio Pfizer per la ricerca in Oncologia 2009
- Prof. Dott. Adrian Ochsenbein, dirigente medico della clinica di medicina Oncologica, Inselspital Berna: Amgen Research Grant 2009
- Dott. Alfred Zippelius, libero docente, Clinica di Oncologia, Clinica universitaria di Basilea: Beneficiario di una borsa di studio per FNS Professori borsisti

Assemblea semestrale di giugno
Il 18 giugno 2009 si è svolta a Berna l'assemblea semestrale estiva del SAKK. Al Centro congressi Blumenberg erano presenti oltre 200 fra oncologi, rappresentanti di case farmaceutiche e del Centro di coordinamento del SAKK. Nelle varie riunioni, membri di gruppi di progetto, gruppi di lavoro e sezioni del SAKK hanno discusso e illustrato sia gli studi in corso sia quelli previsti nei rispettivi ambiti di ricerca.

Durante l'assemblea i membri hanno approvato il bilancio annuale e hanno accolto il nuovo regolamento dell'organizzazione che disciplina la struttura e i processi in seno al Comitato. Tra l'altro si è stabilito che, ai fini di una maggiore trasparenza, in futuro sia i membri del Comitato che i responsabili degli studi manifestino i potenziali conflitti di interesse.

Inoltre, l'assemblea ha eletto all'unanimità il Prof. Donal Hollywood, oncologo al Trinity College di Dublino, Irlanda, come nuovo membro della Commissione scientifica del SAKK. Egli subentra al Prof. Michael Baumann del Politecnico di Dresda.

Donal Hollywood

Il Prof. Dott. Richard Herrmann, presidente del SAKK; il Prof. Dott. Adrian Ochsenbein e il Dott. Jan-Henrik Terwey, Amgen

Assemblea semestrale di novembre

Il 26 e 27 novembre 2009, al Centro congressi di Basilea, si è tenuta l'assemblea invernale del SAKK. Le sessioni dei vari gruppi di ricerca sono state affiancate dal simposio SAKK e dal simposio Satellite, sostenuto dalle ditte PharmaMar e Mundipharma.

Durante il simposio SAKK, il Dott. Adrian Wicki e il Dott. Christoph Mamot, libero docente, vincitori SAKK/Amgen Research Grant 2007, hanno presentato il lavoro premiato nell'ambito degli immunoliposomi. Al Prof. Adrian Ochsenbein dell'Inselspital di Berna è stato consegnato il premio l'Amgen Research Grant/SAKK 2009 di CHF 50 000 per la sua ricerca effettuata sulle cellule staminali e l'immunoterapia.

Dopo la premiazione del Prof. Ochsenbein, la Dott.ssa Silvia Ess del Registro oncologico di San Gallo e il Prof. Beat Thürlimann dell'Ospedale cantonale di San Gallo hanno illustrato i risutlati dello studio «Patterns of care of breast cancer in Switzerland,» che nel 2009, con le loro in parte controverse dichiarazioni sulla terapia oncologica avevano fatto molto discutere in Svizzera.

Il Prof. Beat Thürlimann dell'Ospedale cantonale di San Gallo è stato eletto all'unanimità quale successore del Prof. Richard Herrmann attuale presidente del SAKK che, a scadenza del suo secondo mandato (ultimo possibile), dovrà ritirarsi nel giugno del 2010.

Il Prof. Dott. Richard Herrmann

Il Prof. Dott. Beat Thürlimann

Premio SAKK/Pfizer 2010
Il SAKK e la Pfizer SA di Zurigo-Oerlikon assegnano ogni due anni un premio per la qualità della ricerca medica-oncologica. Il premio di CHF 20 000 sarà consegnato durante l'assemblea invernale del SAKK che si terrà il 25 novembre 2010 prossimo a Basilea. Possono presentare la loro candidatura sia persone sia gruppi svizzeri che operano nel campo della ricerca clinica-oncologica.

Saranno premiati lavori o progetti che contribuiscono a migliorare la qualità e l'efficienza della ricerca clinica-oncologica su bambini e adulti in Svizzera.

Rientrano in questa categoria processi innovativi per il miglioramento dell'organizzazione degli studi e/o della qualità dei dati, nuovi approcci per il miglioramento del reclutamento dei pazienti o contributi alla formazione e al perfezionamento. Potranno essere premiati sia progetti terminati che progetti in corso d'opera e concetti ad alta probabilità di realizzazione.

Il termine di presentazione per i progetti scade il 15 settembre 2010.

SAKK / Dr. Paul Janssen Fellowship
In futuro il SAKK e la Janssen-Cilag SA conferiranno a scadenza annuale una borsa di studio da CHF 50'000. Con tale riconoscimento si intende offrire a giovani medici l'opportunità di lavorare all'estero per quattro mesi in prestigiosi istituti di ricerca, dove possano acquisire maggiori conoscenze sulla ricerca clinica e il know-how necessario per eseguire con successo gli studi previsti.

La borsa di studio sarà attribuita nei prossimi tre anni a scadenza annuale. Potranno presentare la loro candidatura, medici (uomini e donne) impegnati in cliniche svizzere, che stanno seguendo una formazione per diventare oncologi e sono in qualche modo legati al SAKK. Il termine di presentazione delle domande scade il 1° settembre 2010.

Il presidente del SAKK, che presiederà anche la giuria, esaminerà le domande pervenute. Il premio sarà consegnato in occasione dell'Assemblea SAKK nel novembre prossimo. Nella ricerca di un centro di ricerca adeguato, i vincitori saranno affiancati dal SAKK e dalla Janssen-Cilag.

Potrete richiedere il regolamento per la partecipazione ai premi SAKK/Pfizer 2010 a:
Dott. ssa Stephanie Züllig
Centro di coordinamento SAKK
Effingerstrasse 40
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By Dr Peter Brauchli, Director and
Ursula Kühnel, Head Clinical Trial Management

Summary of Activities

In 2009, a total of 831 patients (817 in 2008) were included in 41 clinical trials coordinated by SAKK:

	2009	2008
Total patients from Switzerland	790	773
Total patients from foreign countries	41	44
Total	**831**	**817**

	2009		2008	
	Patients	Trials	Patients	Trials
Total patients in SAKK trials	481	20	532	21
Total patients in trials of cooperative groups (without IBCSG)	132	11	139	13
Total patients in IBCSG trials	173	7	100	6
Total patients in Sendo trials	45	3	46	4
Total	**831**	**41**	**817**	**44**

Trials open for accrual in 2009

Urogenital Cancer

SAKK 08/07 | Docetaxel and cetuximab in patients with docetaxel-resistant hormone-refractory prostate cancer (HRPC). A multicenter phase II trial

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

Lung Cancer

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

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

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

Breast Cancer

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

SAKK 23/03 | Trastuzumab monotherapy followed by the combination of trastuzumab and letrozole in postmenopausal women with ER-positive, HER-2 positive advanced breast cancer resistant to a nonsteroidal aromatase inhibitor. A multicenter two-step phase II 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 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, multi-centre, open-label, phase III study of adjuvant, lapatinib, trastuzumab their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer

IBIS II | International Breast Cancer Intervention Study. A randomised double blind control trial divided into two strata

Leukemia

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

CLL7 | Randomized phase III trial comparing early treatment with fludarabine, cyclophosphamide and rituximab versus deferred treatment in untreated Binet stage A patients with high risk of progression

CLL10 | 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 | Randomized controlled comparison of Imatinib vs Imatinib/IFN-α vs Imatinib high dose (800 mg) and determination of the role of allografting in newly diagnosed CML

GRAALL 2005 | Randomized phase III trial assessing the value of intensive vs standard induction and intensification in a randomized comparison and for B-ALL in a second randomization the benefit of rituximab in addition to chemotherapy and for Ph^+ ALL in a randomized comparison the non-inferiority of an imatinib based induction therapy vs a chemotherapy based induction combined with imatinib

HOVON 81 | A Phase II multicenter study to assess the tolerability and efficacy of the addition of Bevacizumab to standard induction therapy in AML and high risk MDS above 60 years

HOVON 92 / SAKK 30/08 | Standard study to assess the added value of Laromustine in combination with standard remission-induction chemotherapy

Lymphoma

SAKK 36/06 | A multicenter phase II trial testing 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 / IFM 2005-04 | 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

HD13 | Morbus Hodgkin in adults, limited stages

HD14 | Morbus Hodgkin in adults, intermediate stages

HD18 | Therapieoptimierungsstudie in der Primärtherapie des fortgeschrittenen Hodgkin Lymphoms: Therapiestratifizierung mittels FDG-PET

Gastrointestinal Cancer

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

SAKK 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 Sorafenib and Capecitabine in patients with K-ras mutated, locally advanced 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 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

NCIC CTG BI.1 | A phase III study of gemcitabine plus capecitabine (GEMCAP) versus gemcitabine alone in advanced biliary cancer

Melanoma

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

Sarcoma

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

Supportive Care

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

Central Nervous System Cancer

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

New Drugs

S065APOX01 | Phase I dose finding and pharmacokinetic study of intravenous APO010, a recombinant form of human Fas ligand, in patients with solid tumors

S065ST1901 | Phase I dose finding and pharmacokinetic study of the intravenous camptothecin ST1968 in patients with solid tumors

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

SKSD00702 | A phase IB study of the histone deacetylase inhibitor Panobinostat (LBH589) given orally in combination with Carboplatin and Paclitaxel in patients with advanced solid tumors. A SAKK-SENDO phase Ib study

Trials Activated in 2009

Breast Cancer

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

Leukemia

CLL10 | 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

HOVON 92 / SAKK 30/08 | Standard study to assess the added value of Laromustine in combination with standard remission-induction chemotherapy

Lymphoma

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

HD18 | Therapieoptimierungsstudie in der Primärtherapie des fortgeschrittenen Hodgkin Lymphoms: Therapiestratifizierung mittels FDG-PET

Gastrointestinal Cancer

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 Sorafenib and Capecitabine in patients with K-ras mutated, locally advanced rectal cancer. A multicenter phase I/IIa trial

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

NCIC CTG BI.1 | A phase III study of gemcitabine plus capecitabine (GEMCAP) versus gemcitabine alone in advanced biliary cancer

Urogenital Cancer

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

Trials closed in 2009

Gastrointestinal Cancer

NCIC CTG BI.1 | A phase III study of gemcitabine plus capecitabine (GEMCAP) versus gemcitabine alone in advanced biliary cancer
Closed for accrual on 14.07.2009

Leukemias

HOVON 81 | A Phase II multicenter study to assess the tolerability and efficacy of the addition of Bevacizumab to standard induction therapy in AML and high risk MDS above 60 years
Closed for accrual on 18.08.2009

Lung Cancer

SAKK 19/05 | Bevacizumab and erlotinib first-line therapy in advanced non-squamous non-small cell lung cancer (stage IIIB/IV) followed by platinum-based chemotherapy at disease progression. A multicenter phase II trial
Closed for accrual on 01.04.2009

Lymphomas

HD13 | Morbus Hodgkin in adults, limited stages
Closed for accrual on 30.09.2009

HD14 | Morbus Hodgkin in adults, intermediate stages
Closed for accrual on 30.12.2009

Urogenital Cancer

SAKK 08/07 | Docetaxel and cetuximab in patients with docetaxel-resistant hormone-refractory prostate cancer (HRPC). A multicenter phase II trial
Closed for accrual on 08.09.2009

Melanoma

SAKK 50/07 | Temozolomide combined with bevacizumab in metastatic melanoma. A multicenter phase II trial
Closed for accrual on 27. 04. 2009

Sarcoma

EuroEwing 99 | Studie zur Behandlung des Tumors der Ewing-Gruppe
Closed for accrual on 30. 09. 2009

Central Nervous System Cancer

SAKK 70/03 | Whole brain radiotherapy in combination with gefitinib (Iressa) or temozolomide (Temodal) for brain metastases from non-small cell lung cancer (NSCLC). A randomized phase II trial
Closed for accrual on 02. 04. 2009

Project Group Breast Cancer


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Presidents:

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

Objectives

The Breast Cancer Project Group (BCPG) aims to facilitate and conduct clinical and translational research in breast cancer and to collaborate with international research groups (i.e. IBCSG, BIG, EORTC). In the currently open trials SAKK 22/99, 92/08, and IBCSG 22, 23, 24, 35, 36 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 relations.

The reintegration of the gynecologists, an important objective for the BCPG, is still ongoing. As of 2009, a gynecologist is co-president of the BCPG. The «Arbeitsgemeinschaft für Onkologie» (AGO), has agreed not to develop projects in breast cancer and to focus on gynecologic malignancies. Several gynecologists are members of the BCPG.

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 92/08 and SAKK 24/09 studies, health economic issues in the SAKK 24/09 trial, radiotherapy trials such as IRMA and IBCSG-38-09, and randomized surgical interventions such as in a currently discussed trial of the Austrian breast group, ABCSG 28, POSYTIVE.

Activities

Trials Activated in 2009

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

The aim of this trial is to evaluate the effects of F511 cream on the occurrence of palmar-plantar erythrodysesthesia (PPE) in patients with breast cancer treated with pegylated liposomal doxorubicin.

The trial was activated by Swissmedic in August 2009, and by the end of the year, 16 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

The portfolio plan for the next years contains the following trials:

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 first line aromatase inhibitor: a randomized phase II trial*
The primary objective of the trial is to assess the activity of the combination of fulvestrant and AZD6244 in patients progressing after first line AI. This trial is planned to be conducted in collaboration with a Belgian cooperative group.

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 II trial*
The primary objective of the trial is to demonstrate reduced toxicity of metronomic chemotherapy in com-

bination with bevacizumab compared to a standard paclitaxel/bevacizumab regimen in metastatic breast cancer.

SAKK 20/09 | *CYP2D6 to predict the efficacy of tamoxifen in metastatic breast cancer*

The primary objective of the trial is to assess the influence of CYP2D6 mutations on tamoxifen efficacy in patients with advanced breast cancer. This trial is planned to be conducted in collaboration with a Belgian cooperative group.

SAKK 26/10 | *Swiss utility protocol, OncotypeDX*

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.

NCI-Canada MA.32 | *Adjuvant metformin in ER/PR neg., HER2 positive BC*

The primary objective of the trial is to assess the activity of metformin, an oral antidiabetic agent and an inhibitor of mTOR, in early breast cancer.

IRMA trial | *Randomised Trial of Accelerated Partial Breast Irradiation*

The IRMA (Innovazioni nella Radioterapia della MAmmella) trial compares WBRT (Whole Breast Radio Therapy) and 3D conformal radiotherapy to a partial breast planning target volume. The primary objective of the trial is to establish equal efficacy of WBRT and accelerated partial breast irradiation.

ABCSG 28, POSYTIVE | *Austrian ABCSG 28 study of breast surgery vs. none in metastatic BC*

The primary objective of the trial is to assess the potential benefit of breast surgery in the presence of distant metastases.

Collaboration with/participation in other groups

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

The group aims at covering as many clinical situations in gastrointestinal cancer as possible with interesting protocols. A key interest is translational research, since predictive markers are desperately needed in this tumor group. Whenever possible, international collaboration should be promoted. However, looking at the current health care environment, one future focus of the group should become quality assurance and outcomes research and the definition of treatment guidelines for clinical situations, where there are no solid data to guide decisions. A good example is the standardization of chemoembolization in Switzerland, which was a byproduct of developing protocol 77/09 in hepatocellular carcinoma.

Activities

Trials Activated in 2009

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 Sorafenib and Capecitabine in patients with K-ras mutated, locally advanced rectal cancer. A multicenter phase I/IIa trial*

Accrual into the first dose level of this trial is completed and the terms for continuation of the trial are discussed.

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

NCIC CTG BI. 1 | *A phase III study of gemcitabine plus capecitabine (GEMCAP) versus gemcitabine alone in advanced biliary cancer*

Closed Trials

NCIC CTG BI. 1 | *A phase III study of gemcitabine plus capecitabine (GEMCAP) versus gemcitabine alone in advanced biliary cancer*

Closed for accrual on 14. 07. 2009

Strategic elements for the next two years

Rectal cancer has been identified as a tumor entity, where rapid accrual is possible in Switzerland. To develop follow-up protocols for SAKK 41/07 and 41/08 is thus a priority. The collaboration with Santésuisse for trial 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 about models, how SAKK can provide support for decentralized trial activites. Another priority of the group is the conduct of studies in pancreatic cancer, since progress in this field is painfully slow.

Portfolio Plan

The following trial has passed the administrative hurdles and will be soon open for accrual:

SAKK 77/09 and SASL 30 | *A phase I open label/phase II randomized, double-blind, multicenter trial investigating the combination of everolimus and TransArterial Chemo-Embolisation (TACE) with doxorubicin in patients with hepatocellular carcinoma*

Thus, the project group will present a complete portfolio for the treatment of this increasingly important tumor entity.

The following protocols are close to completion:

– Protocol SAKK 75/08 on non-metastatic esophageal cancer will build on previous experience of the group (SAKK 75/06) combining radiotherapy, concomitant cisplatin, docetaxel and cetuximab. In a randomized phase III setting, the impact of adjuvant cetuximab will be examined. This trial will be performed in collaboration with the German group headed by Prof Stahl.
– The impact of Lapatinib in metastatic gastric cancer is the focus of a randomized phase III trial of the European Organisation for Research and Treatment of Cancer (EORTC) headed by Arnaud Roth.

Under discussion are protocols in metastatic rectal cancer, neuroendocrine cancer, a protocol on the oxaliplatin infusion duration in colorectal cancer, a protocol on capecitabine and panitumumab in elderly patients with colorectal cancer, and a protocol in the adjuvant treatment of pancreatic cancer comparing chemotherapy +/- radiotherapy +/- erlotinib in a 2 x 2 design (RTOG 0848).

Collaboration with/participation in other groups

Unfortunately, the collaboration with the National Cancer Institute Canada (NCIC) has been halted, since the protocol in metastatic biliary tract cancer has been closed due to the definition of a new standard treatment for this disease. A collaboration with the German group headed by Prof Stahl for a randomized trial in localized esophageal cancer has been established and the protocol will probably be activated early in 2010. Another international collaboration will be the protocol of Arnaud Roth with the EORTC on the impact of lapatinib in HER1/2 positive metastatic gastric cancer. A participation of the group in the American adjuvant pancreatic cancer trial RTOG 0848 would also be an interesting option to increase the visibility of the SAKK in the US and because of the relevant trial questions (impact of erlotinib and radiotherapy). Finally, the quest for an adjuvant trial participation in colon cancer will be only feasible in the context of an international collaboration.

Project Group Leukemia

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

Objectives

We offer clinical studies covering the main topics in acute and chronic leukemia, however not 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 as for example 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 project group was planning the foundation of a Swiss registry for acute leukemia but this part seems to be much more difficult than anticipated. The group will check to take over the lead in Phase III trials. The objective to have active membership 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.

Activities

Trials Activated in 2009

Phase III trial:

CLL10 (Chronic Lymphocytic Leukemia) | *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*

The hypothesis is that BR has a non-inferior therapeutic efficacy compared with FCR, but a better safety profile causing less myelosuppression, infections and secondary neoplasia.

The total accrual target is 550 patients. The trial was activated in January 2009.

Phase II trial:

AML (Acute Myeloid Leukemia)

HOVON 92 / SAKK 30/08 | *Standard study to assess the added value of Laromustine in combination with standard remission-induction chemotherapy. A multicenter phase II trial*

The objective is to determine the feasibility of Laromustine when given at three possible dose levels together with standard induction cycles I and II in patients with AML/RAEB with IPSS $\geq$ 1.5 in a prospective comparison to standard induction cycles I and II without Laromustine. It is also to investigate the clinical efficacy of Laromustine in combination with remission induction chemotherapy cycles I and II with regard to complete remission rate at different dose levels of Laromustine. The trial was activated on April 2, 2009.

Closed Trial

SAKK 63/03 | *Blood and bone marrow banking in SAKK leukemia trials*

The main objective of the study was to preserve material for later use in biological studies which will be submitted to SAKK in the future. The members of the SAKK Leukemia Project Group have decided to bank the material centrally in Aarau. It was collected at the time of inclusion of a patient into one of the ongoing trials. The project was supervised by a banking committee. The database documenting the collection and central storage of material resides at the SAKK Coordinating Center. A remote data entry facility has been developed to this effect. It also provides to the researchers an overview of the banked material. 65 samples have been collected. Due to the difficulty of accrual over 6 years, the SAKK board decided to close the project in September 2009. The samples are being allocated to different projects after acceptance by the SAKK board.

Strategic elements for the next two years

- 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 relapsed AML or CLL;
- to stimulate translational research projects (prognostic MRD (Minimal Residual Disease) as well as study of leukemic stem cells, leukemogenesis, genomic and proteomic) as this was poorly done for the last years. We need to have more collaboration with research laboratories;
- to improve the input of SAKK in the collaboration with international study groups as far as clinical phase III trials are concerned;
- to evaluate the feasibility of the set-up of a Swiss registry for acute leukemia.

Portfolio Plan

Trials

Phase III:

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 trial will be activated in 2010.

Phase II:

SAKK 31/08 | *A Phase II multicenter study to assess the feasibility and efficacy of Clofarabine, Gemtuzumab Ozogamicin and high dose Cytarabine for treatment of relapsed/refractory AML in young patients (< 60 years).*

The main objective is to evaluate the efficacy, safety and tolerability of Clofarabine, cytarabine and Gemtuzumab Ozogamicin (CLAG) combination in the setting of relapse/refractory AML.

The trial will be initiated only if the drug Gemtuzumab Ozogamicin (Mylotarg®) will be delivered for free to the patients. An answer from Pfizer is awaited for April 2010.

Phase I:

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 will be activated in 2010.

Follow up Trials

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 in 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 as 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 will be activated in 2010.

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 detect 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 seve-

rity of toxicities and the durations of neutropenia and thrombocytopenia) and select the 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) as regards the selected dose level of Drug X. 2. To assess in a randomized comparison the effect of Drug X on the CR rate.

The trial is in the process to be activated in 2010 if accepted by the SAKK board.

CMLV | Chronic Myeloid Leukemia with the German Study Group, which should follow the CMLIV protocol

The trial is still under discussion in the project group and in the German Study Group.

A follow up trial of the SAKK 30/07 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 a new drug sapacitabine with standard of care.

The trial is under discussion in the project group.

Collaboration with/participation in other groups

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

- Project Group New Anticancer Drugs
- 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-LALA, Belgium in ALL
- The German CLL Study Group (GCLLSG) in CLL
- The German CML Study Group (GCMLSG) in CML
- The European APL group
- The European Leukemia Network
- The European Group for Blood and Marrow Transplantation (EBMT)

Project Group Lung Cancer


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Presidents:

1 PD Dr Miklos Pless, Department of Medical Oncology and Tumor Center, Kantonsspital Winterthur

2 Prof Dr Walter Weder, Division of Thoracic Surgery, University Hospital Zurich

Objectives

- The Lung Cancer Project Group creates and organizes relevant studies to treat as many Non-Small Cell Lung Cancer (NSCLC) patients in trials (stage IV)
- 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.

Activities

Closed Trials in 2009

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

Closed after successfully completing its recruitment.

Strategic elements for the next two years

- to perform the follow up studies for stage IV (SAKK 19/09), stage IIIB (SAKK 16/08) and also a new Small-Cell Lung Cancer trial (SAKK 15/08);
- to join a new adjuvant study for early stage NSCLC;
- to establish a cooperation with other cooperative groups, e.g. the Belgian group in Leuven and Freiburg i. B.;

– 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.

Portfolio Plan

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 will be activated in Q1 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.
The trial will be activated in 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 trial proposal has been approved by the SAKK Board. It will be submitted to Ethic Committees in Q2 2010.

Collaborations with/participation in other Groups:

– Freiburg i. Breisgau
– Leuven (Belgium)
– Novi Sad (Serbia)

Project Group Lymphoma


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Presidents:
1 PD Dr Nicolas Ketterer, Centre Pluridisciplinaire d'Oncologie, University Hospital Lausanne (CHUV) (until December 31, 2009)
2 PD Dr Emanuele Zucca, IOSI, Instituto Oncologico della Svizzera Italiana (starting January 1, 2010)

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 ameliorate the management and the treatment of patients with lymphoma, by developing and leading some original 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. 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.

Activities

Trials Activated in 2009

HD18 | *Therapieoptimierungsstudie in der Primärtherapie des fortgeschrittenen Hodgkin Lymphoms: Therapiestratifizierung mittels FDG-PET*

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*

Closed Trials

HD13 | *Qualitätssicherungsprotokoll zur Toxizitätsreduktion in der Primärtherapie des frühen Morbus Hodgkin*

HD14 | *Qualitätssicherungsprotokoll zur Effektivitätssteigerung in der Primärtherapie des intermediären Morbus-Hodgkin*

SAKK 36/06 | *A multicenter stratified phase I trial testing Everolimus (RAD001) for the treatment of patients with newly diagnosed and relapsed or chemotherapy resistant mantle cell lymphoma*

Strategic elements for the next two years

The project group will adjust its activities to comply with the rules approved by the SAKK Board in 2009. One very important step is to take advantage of the presence of the international advisor in the project group meetings. The collaborations with other international collaborative groups will be the 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 of the SAKK.

The most important issue is to have again an active study for follicular lymphoma. With respect to this, a very promising collaboration is ongoing with the Nordic Lymphoma Group for the development of a common study. Both groups agreed to address the feasibility of chemotherapy-deferral strategies in the front line treatment of follicular lymphoma.

Portfolio Plan

New studies will have to be set up in follicular lymphoma, mantle cell lymphoma and multiple myeloma. The HD16 trial for Hodgkin Lymphoma should be opened.

SAKK 65/08 | *In collaboration with the Phase I project group and the leukemia 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 will be activated in 2010.

Collaboration with/participation in other groups

– While, as suggested by the SAKK Board, the collaboration with the Intergroupe Francophone du Myélome (IFM) will have to be rediscussed, the project group will keep seeking an active collaboration in other selected large international projects, allowing a reinforcement of our collaboration with other large cooperative international groups as:
– German Hodgkin Study Group (HD trials)
– Nordic Lymphoma group (Follicular lymphoma trial)
– European Mantle Cell Lymphoma Network

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 increase experience and set up a central coordination for early drug development.
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 provide SAKK with a constant flow of new drugs for Phase II trials.

Activities

Portfolio Plan

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 is developed in collaboration with the Project Group Leukemia and the Project Group Lymphoma. Patients will be 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 performed in two centers in Switzerland and in one center in Italy

Collaboration with/participation in other groups

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

Project Group Urogenital Tumors


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Presidents:
1 PD Dr Silke Gillessen, Department of Medical Oncology, Kantonsspital St. Gallen
2 Prof Dr George Thalmann, Department of Urology, Inselspital, University Hospital Bern

Objectives

- The Project Group Urogenital Tumors (PGU) aims to conduct clinical and translational research in the field of urogenital tumors, with a focus on prostate cancer involving all disciplines interested in the topic.
- The integration of all disciplines involved in the treatment of urogential cancers is warranted and is still ongoing. Over the last months a vivid interest in the group and specifically in questions concerning prostate cancer from the radiooncologists has been evolving.
- We hope to further enhance also the interest of young urologists in our group and therefore develop more trials of urological interest.
- With growing experience in conducting clinical studies more translational studies should be included in these trials, collaborators for these studies have to be encouraged to become members of the group.
- The PGU aims to collaborate with international research groups like the Medical Research Council (MRC).

Activities

Trials Activated in 2009

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

Closed Trials

SAKK 08/07 | *Docetaxel and Cetuximab as second line treatment in patients with progressive castration resistant prostate cancer refractory to docetaxel: A multicenter Phase II trial*

Strategic Elements for the next two years

- to focus on prostate cancer, specifically in the two situations, where we see medical need: First, early asymptomatic and oligosymptomatic slowly progressing castration resistant disease before chemotherapy with docetaxel and second, second line therapy after docetaxel failure;
- to focus on intensifying 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 radiooncologists 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 MRC.

Portfolio Plan

According to the above mentioned strategies we are preparing a successor trial of SAKK 08/08 (using Metformin instead of Everolimus) and a successor trial of SAKK 08/07 (planed is a combination therapy with ASA404 and carboplatin/paclitaxel in second line chemotherapy).

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 (Doecetaxel +/-Cetuximab) is of interest. Translational research could be helpful to define biomarkers for stratification, but results are still pending. For a Phase III trial we need international collaboration.

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 MD Tom Powles.

A potential collaboration with the German Testicular Cancer Group is planned in the field of follow up of testicular cancer patients and potentially in seminoma II A and B.

Section Clinical Research Coordinators (CRC)

Presidents:

1 Christine Biaggi Rudolf, SAKK Coordinating Center Bern
2 Julia Rengier-Styles, Centre Pluridisciplinaire d'Oncologie, University Hospital Lausanne (CHUV)

Short introduction

2009 has been a year of stability in the Presidency of the Section and in our activities, with no major changes being implemented.

Activities 2009

In January we had our two-day annual meeting for Clinical Research Coordinators at the SAKK Coordinating Center in Bern. It was again a very intense program with a lot of interesting presentations in various fields of cancer research as well as some excursions into Good Clinical Practice (GCP) and overall clinical trial management.
It has become routine that the first morning of those two days is particularly dedicated to new section members who have only recently started their work as a CRC at a center. Overall attendance was very high; some 58 certificates of attendance were handed out, and the feedback we received was on the whole very positive.

In November the Section met at the semi-annual meeting in Basel. The focus of this meeting was the presentation of the newly structured Clinical Trial Management Unit at the SAKK Coordinating Center, updates from the SAKK regulatory unit – explaining the «Leit-EK-System» – and, as main topic of the session, a brainstorming and discussion of what the CRC section could look like in the future.
We have discovered that the ideas of what the section should focus on or should constitute varies widely. There is such disparity between different regions and/or centers that the task of fulfilling the needs of all our CRCs is quite a Herculean task.

It was then decided that we should rethink the arguments (pros and cons) which were discussed at this meeting and that the CRC section presidents would form a task group with some CRCs and Study Nurses to tackle this subject and come forward with a proposal on how and by whom a «modern» CRC section should be run, as well as defining its actual function.

Outlook

As written above, the goal for the year 2010 is to re-structure our section, make it become a well organized, focused working section.

Unfortunately, the educational program for clinical research professionals, especially for CRCs which was planned to start this year could not be offered by the organizers yet. Personnel changes at the SAKK CC forced the launch of the program to be postponed until the year 2010. Collaboration between the CTU Bern and the SAKK CC however is still strengthening; we hope some interesting projects may be developed in the near future.

In 2010 we will again organize our two-day annual meeting (February 1 and 2) as well as a section meeting in November in the framework of the SAKK semi-annual meeting.

Section Pathology

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

Short Introduction

The section of 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 diagnose; the goal of such a review is quality assurance
- Establishment of novel predictive tests, e.g. KRAS testing in colorectal cancer
- Translational research requires tissue banking; pathologists are involved in collection of biomaterial and establishment of biobanks

Activities 2009

The section Pathology is involved in about 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 group (SAKK 16/08, SAKK 17/04), lymphoma (SAKK 38/07, SAKK 36/06), melanoma (SAKK 50/07) and urogenital tumors (SAKK 08/07, SAKK 08/08), head and neck (SAKK 10/94) and others. These activities include the collection of biomaterial, translational research and predictive tests. The completion of patient forms (P-form) requires the engagement of many pathologists.

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 biobanks in Switzerland

Section Trial Nurses

President: Vacant
Contact person: Christel Böhme, Kantonsspital St. Gallen

Short introduction

The group members, with a multifaceted nursing background hold different positions in Swiss hospitals. All work with patients treated in SAKK clinical trials.
Since many years we evaluate draft protocols for their practical and nursing implications and patient considerations, as well as CRF comprehensibility.
In this function we serve as a part of the SAKK internal protocol review process.
Additionally, on each SAKK protocol with a medical treatment a trial nurse is assigned as a contact person for nursing issues.
Our goal is to make a contribution to assure high-quality clinical trial performance, patient understanding of the informed consent and safety.

Activities 2009

- Review of several SAKK protocols
- Meeting at the semi-annual meeting in Basel
- Exchange of knowledge throughout the year

Outlook

- Continue our work within the Internal Review Board
- Provide support for nursing issues in ongoing SAKK trials
- Confident that we will provide continuing support to the work of clinical trial to the work of SAKK. However, our exact role and future structure is at the moment under discussion, due to the current restructuring of the sections: Clinical Research Coordinators and Clinical Trial Nurses

Network for Cancer Predisposition Testing and Counseling (CPTC)


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

Short introduction

The aims of the Network for CPTC are
- to harmonize the clinical practice of counseling and management of at-risk individuals;
- to collect clinical data and mutation screening results of families with inherited cancer predisposing syndromes;
- to consolidate the collaboration with the reference molecular laboratories for 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 2009

More than 400 new families have been managed in the 17 centers providing genetic counseling and evaluation for cancer predisposition testing according to the Swiss regulation (cf. KVL/OPAS/OPre art. 12, let. v).

Swiss referral guidelines for genetic counseling and evaluation for BRCA1/BRCA2 testing have been finalized by the Network. These guidelines have been prepared to help clinicians identify the situations where a familial aggregation or a syndrome of hereditary breast/ovarian cancer should be suspected, and an adequate management could be proposed. These guidelines have been approved by the Swiss Society of Medical Genetics, the Swiss Society of Senology, the Swiss Society of Medical Oncology and the Swiss Society of Gynecology and Obstetrics.

A research project based on clinical and molecular data collected by the members of the Network has been submitted. The aim of this project is to evaluate the incidence of germ-line alterations in a panel of breast cancer susceptibility genes in BRCA1/BRCA2-mutation negative families using a resequencing array approach.

Outlook
- to manage individuals identified at high-cancer risk according to standard clinical practice in Switzerland;
- to publish the Swiss guidelines for genetic counseling and evaluation for BRCA1/BRCA2 testing;
- to remain participating in the 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);
- to assess oncogenetic activity and results of BRCA1/BRCA2 germ-line mutation screening in Switzerland (a PhD thesis project of a genetic counselor).

Network for Outcomes Research


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President:

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

Vice-President:

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

Objectives of the Network

The aim of the network is to promote interdisciplinary outcomes research in oncology. The network may be consulted by any SAKK project group, working group or section to provide advice on outcomes research-related aspects in ongoing or planned trials.

The network performs health economic evaluations (HEA) as sub-projects alongside SAKK trials where considered appropriate. One aim is to establish standard procedures for prospective health economic analyses alongside clinical trials. Furthermore, the network actively develops outcomes research-orientated research projects in collaboration with third parties.

Literature based HEA of established or emerging cancer treatments, which might be of importance for the Swiss healthcare system, are also performed.

Activities in 2009 and Outlook

A key activity is to perform HEA alongside clinical trials. Although Switzerland has no institution like NICE 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 health-care decision making.

Prospective health economic evaluations were implemented as sub-projects in four SAKK trials. Data collection procedures and clinical report forms were developed and the preference-based quality of life questionnaire EQ-5D was included.

Retrospective data collection for some ongoing SAKK trials was further developed. For two trials protocol amendments are written in order to cover revised HEA methodology.

An outcomes research study on «delivery of care at the end-of-life of cancer patients in Switzerland», in collaboration with the insurance company Helsana and four cancer registries, was approved by the SAKK Board in 2009. Technical aspects of this study were solved in cooperation with the participating registries. Legal issues and data protection as well as ethical aspects of the study are now being elucidated and the study will be brought forward with high priority.

Two new literature based HEA were performed:

Trastuzumab beyond progression: a cost-utility analysis

Based on the study «*Trastuzumab beyond progression in human epidermal growth factor receptor 2-positive advanced breast cancer: a german breast group 26/breast international group 03-05 study» (von Minckwitz G, du Bois A, Schmidt M, et al.)*

It was submitted for publication in February 2010.

Assessment of use of cetuximab in lung cancer patients

Based on the results of the FLEX study *(Pirker R, Pereira JR, Szczesna A, von Pawel J, Krzakowski M, Ramlau R, Vynnychenko I, Park K, Yu CT, Ganul V et al: Cetuximab plus chemotherapy in patients with advanced non-small-cell lung cancer (FLEX): an open-label randomised phase III trial. Lancet 2009, 373(9674):1525-1531.)*

Submission for publication is planned for 2010.

Networking activities

At the semi-annual SAKK meeting in November 2009, we could welcome Prof John Brazier, Health Economics and Decision Science at the School of Health and Related Research, University of Sheffield, U.K. Prof Brazier gave a presentation on "Measuring health benefits for economic evaluation – the case for the QALY".

Trials

SAKK 35/03 (closed) | *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. An amendment for the revised HEA sub-project will be prepared in 2010.

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 (will be opened 2010) | *A phase I open label/phase II randomized, double-blind, multicenter trial investigating the combination of everolimus and Trans-Arterial ChemoEmbolisation (TACE) with doxorubicin in patients with hepatocellular carcinoma eligible for TACE*

Prospective HEA sub-project included.

SAKK 75/08 (will be opened 2010) | *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 (will be opened 2010) | *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 in Phase II included.

SAKK 89/09 (start 2010) | *End-of-life delivery of care patterns in Swiss cancer patients.*

Project ongoing.

Collaboration with/participation in other groups

The network initiates project-level cooperation with different institutions active in the field of cancer, e.g. with insurance companies, National Institute for Cancer Epidemiology and Registration (NICER), and the Children's Cancer Registry.

SAKK and Collaborating Groups

Lung Cancers

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Breast Cancer

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Resoconto annuale

Resoconto annuale dal 1° gennaio al 31 dicembre (in CHF)	**2009**	**2008**
Reddito di esercizio		
Contributi per la ricerca SBF[1]	4 019 850.00	3 930 520.00
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Ricavi collaborazioni industriali	4 126 604.45	2 268 112.60
Ricavi gruppi di studio esteri	89 910.11	0.00
Redditi bollettino sul cancro	326 490.00	281 885.00
Donazione, Legati & Eredità	57 569.80	40 720.00
Redditi vari	287 745.52	484 918.85
Totale reddito di esercizio	**10 428 831.88**	**8 433 951.03**
Spese di esercizio		
Costi per studi vari	– 824 010.07	– 529 278.75
Contributi per la ricerca IBCSG[3]	– 250 000.00	– 250 000.00
Contributi per la ricerca Centri	– 3 009 964.17	– 2 699 123.95
Costi di trasferta e viaggi di rappresentanza	– 167 700.44	– 241 480.75
Altre spese di esercizio	– 192 479.10	– 63 649.62
Totale spese di esercizio	**– 4 444 153.78**	**– 3 783 533.07**
Subtotale 1	5 984 678.10	4 650 417.96
Costi di coordinamento		
Costi per il personale	– 5 016 747.44	– 4 080 476.39
Altri costi di coordinamento	– 1 042 005.77	– 831 077.70
Totale costi di coordinamento	**– 6 058 753.21**	**– 4 911 554.09**
Subtotale 2	– 74 075.11	261 136.13
Risultato finanziario		
Reddito finanziario	18 536.98	131 068.35
Oneri finanziari	– 4 695.73	– 117 838.11
Totale risultato finanziario	**13 841.25**	**13 230.24**
Subtotale 3	– 60 233.86	– 247 905.89
Variazione fondi		
Scioglimento e accantonamenti	3 133.00	154 628.40
Scioglimento Fondi	30 568.00	0.00
Totale variazione fondi	**33 701.00**	154 628.40
Subtotale 4	– 26 532.86	– 93 277.49
Attività al di fuori del periodo		
Attività al di fuori del periodo considerato	19 736.66	58 024.39
Scioglimento di accantonamenti non necessari	– 126 850.80	0.00
Totale attività al di fuori del periodo considerato	**– 107 114.14**	58 024.39
Risultato complessivo	**– 133 647.00**	**– 35 253.10**

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/Oncosuisse

3 International Breast Cancer Study Group IBCSG

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