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

Rapport annuel

09

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Editorial

Actualités 2009

Par le Pr Richard Herrmann | Président du SAKK

Le présent rapport annuel rend compte des activités du Groupe Suisse de Recherche Clinique sur le Cancer (SAKK) en 2009. Les résultats dont il fait état sont, une fois de plus, impressionnants. Je tiens tout particulièrement à souligner qu'outre les tâches relevant de sa mission première, le SAKK a à son actif d'importantes réalisations gages d'un fonctionnement optimisé. En vue notamment de professionnaliser ses relations extérieures, notre organisation a ainsi étoffé ses effectifs. Elle s'est aussi dotée de nouveaux règlements, qui accroissent la transparence de ses procédures internes. Autant d'évolutions qui contribuent à imposer le SAKK, tant en Suisse que chez ses voisins européens, comme un acteur compétent en matière de recherche clinique. Mais l'heure n'est pas à la contemplation satisfaite des acquis, tant les défis que nous réserve l'avenir restent multiples.

Avec les autorités (Swissmedic, OFSP) et les commissions d'éthique, nous aspirons à une collaboration empreinte de confiance dans le cadre des attributions conférées par les lois et ordonnances en vigueur. Nous attendons aussi de ces instances qu'elles soutiennent notre travail et que, conformément à la loi, elles œuvrent à ce que la recherche clinique en Suisse soit encouragée et non pas entravée. Nous nous retrouvons trop souvent dans la position du quémandeur et déplorons une perte de vue de l'objectif ultime, qui est d'agir pour le bien des patients cancéreux. D'où, en mon sens, la nécessité d'afficher ici des positions claires, qu'il convient de défendre aussi auprès de l'opinion publique, et de faire front uni avec d'autres acteurs de la recherche clinique en Suisse.

La conception de nouvelles études comporte des défis d'une autre nature. Notre quotidien clinique est de plus en plus déterminé par les avancées de la biologie moléculaire. Le cancer du sein et le cancer du poumon n'existent ainsi plus en tant que tels. Les sous-classifications entraînent une différenciation des stratégies thérapeutiques. Pour la recherche clinique, cela signifie que, dans bien des maladies, une étude ne porte désormais plus que sur un sous-groupe et qu'un nombre resteint de patients peut être inclus dans chacune. Aussi, pour atteindre les effectifs annuels de patients requis, devons-nous ouvrir davantage d'études. Concrètement, cette situation nous amène à élargir les coopérations internationales car, dans de nombreuses indications, nos activités en Suisse ne nous permettent plus d'obtenir des résultats probants. En outre, nous devrons identifier d'autres domaines de l'oncologie où des possibilités de recherche sont envisageables. L'étude 41/06, qui porte sur l'opportunité du traitement d'entretien par le bevacizumab dans le carcinome colorectal, en constitue un exemple. Les procédures diagnostiques, p. ex. dans le cadre du suivi, ainsi que la radio-oncologie et la chirurgie sont des domaines d'investigation supplémentaires. Heureusement, nous avons de nombreux collègues qui investissent leurs compétences et leur énergie dans ce travail et se mobilisent pour relever des défis audacieux.

Le Centre de coordination du SAKK à Berne s'est érigé au cours des dernières années en centre de compétences pour l'organisation d'études cliniques à l'échelle nationale et internationale. Je suis témoin de l'engagement dont les collaboratrices et collaborateurs font preuve dans leur travail ainsi que de l'évolution positive des interactions entre le Centre de coordination et les membres hospitaliers du SAKK. Je profite de l'occasion pour remercier de leurs précieux efforts tous les intervenants, en particulier le Dr Peter Brauchli, Directeur du SAKK, et son équipe dirigeante.

La viabilité des activités du SAKK dépend du soutien de divers bailleurs de fonds, dont le premier est la Confédération via le Secrétariat d'Etat à l'éducation et à la recherche (SER). Nous bénéficions d'apports supplémentaires au titre de coopérations avec l'industrie ainsi qu'en provenance de la Ligue suisse contre le cancer, de la Recherche suisse contre le cancer, de la Fondation suisse pour la recherche clinique sur le cancer et de particuliers sous forme de dons. Nous exprimons ici notre gratitude à tous ceux qui sont solidaires de notre action.

Groupe Suisse de Recherche Clinique sur le Cancer SAKK

Activités au Centre de coordination

Par le Dr Peter Brauchli | Directeur du SAKK

Quelle est la vocation du SAKK?

Le Groupe Suisse de Recherche Clinique sur le Cancer (SAKK) est un groupe coopératif qui intervient en Suisse pour favoriser le développement des traitements anticancéreux existants et évaluer l'efficacité et la tolérance de nouvelles options thérapeutiques. Il veille à ce que le ré-sultat de ces recherches profite le plus vite possible aux patients. Conjointement avec le Groupe d'Oncologie Pédiatrique Suisse (SPOG), le SAKK est chargé par le Secrétariat d'Etat à l'éducation et à la recherche (SER) de la conduite de la recherche clinique en oncologie. Le Centre de coordination du SAKK assiste les investigateurs dans le développement, la réalisation et l'évaluation d'études menées chez des patients cancéreux, toutes les modalités – chirurgie, radiothérapie et chimiothérapie – étant explorées. Grâce à son résaux, les cinq hôpitaux universitaires ainsi que douze autres établissements hospitaliers sont associés à la recherche clinique académique en tant que membres du SAKK.

En 2009, des progrès importants ont été réalisés qui nous permettent d'intervenir de façon plus efficace et d'atteindre nos objectifs.

Règlement d'organisation du Comité

Approuvé en juin par l'Assemblée des membres, le règlement d'organisation a été porté à la connaissance du SER, dont il a reçu l'aval. Le Comité du SAKK opère conformément aux principes de gouvernance institutionnelle applicables aux organisations à but non lucratif et procède à la sélection des études sur la base de critères internationalement reconnus. Le texte énonce clairement les paramètres et les documents sur lesquels le Comité doit se fonder pour statuer sur un projet d'étude. L'obligation de déclaration des conflits d'intérêts y est formalisée. De plus, le règlement instaure le principe contraignant d'une procédure en deux temps avec examen initial et examen final.

Règlement relatif aux groupes de projet

Le règlement relatif aux groupes de projet a été approuvé en novembre par l'Assemblée des membres. Il définit les critères qui régissent la qualité de membre d'un groupe de projet et investit formellement les groupes de projet d'un droit de proposition quant aux projets à l'égard du Comité. Il impose en outre la participation d'un expert international aux séances des groupes de projet.

Ces règlements sont deux rouages essentiels à une collaboration efficace entre les groupes de projet et le Comité. Ils sont les garants de l'indépendance des organes, de la transparence des opérations et du développement de projets arrivés à maturité grâce à un processus itératif.

L'intervention du Centre de coordination est indispensable au déroulement optimal des opérations. L'unité de coordination d'études a été développée en vue de faire avancer les projets de façon plus efficace à l'avenir. En outre, un Proposal Review Committee chargé d'encadrer la procédure d'examen des projets d'étude depuis un stade précoce est institué spécifiquement pour chacun d'eux.

Stratégie

Le Conseil scientifique du SAKK est composé de six experts étrangers indépendants. En février 2009, celui-ci, le Comité du SAKK, les présidents des groupes de projet et des représentants du Centre de coordination du SAKK se sont réunis une deuxième fois en vue d'examiner la stratégie et la position du SAKK. Les recommandations qui se sont

dégagées de cette rencontre ont été développées et déclinées en objectifs à long terme à l'occasion de la retraite d'octobre 2009.

Inclure davantage de patients dans les études et endosser aussi un rôle de premier plan dans la réalisation d'études internationales, tel est le but déclaré du SAKK. Les membres du Comité ont par ailleurs défini les priorités et objectifs des groupes de projet du SAKK ainsi que les exigences posées à ces derniers.

Lors de la retraite, l'opportunité d'inciter les médecins investigateurs à réaliser davantage d'études de phase III dans les principales indications et à intégrer dans leur démarche les aspects de la recherche translationnelle, de la recherche sur l'évaluation des résultats, du rapport coûts-bénéfice ainsi que de la qualité de vie et du suivi thérapeutique a été affirmée.

En réponse à la productivité en hausse de notre réseau, un plus grand nombre de priorités doivent être établies.

Le Comité a repris certaines suggestions du Conseil scientifique et a érigé les points suivants en objectifs pour les prochaines années:

- instauration de comités des tumeurs dans les centres membres;
- création de conditions cadres et d'incitations propres à favoriser la participation d'oncologues privés aux études du SAKK;
- élargissement des activités de recherche à d'autres types de cancer tels que tumeurs de la tête et du cou ou du système nerveux central, cancers gynécologiques, sarcomes, mélanomes et cancer du pancréas;
- spécialisation dans des maladies très rares;
- promotion et extension de la collaboration avec santésuisse;
- amélioration de la collaboration internationale, notamment avec les petits pays (centres et groupes scandinaves, hollandais, belges, autrichiens, polonais, hongrois, etc.);
- obtention d'une procédure d'autorisation simplifiée auprès des commissions d'éthique et de Swissmedic;
- encadrement des petits centres par un «flying data manager».

Lors d'une rencontre entre le Comité, les présidents des groupes de projet et le Centre de coordination à l'occasion de l'Assemblée semestrielle de novembre, les exigences posées aux groupes de projet et les directives stratégiques ont été communiquées. Ces idées seront restituées dans la demande de financement adressée prochainement au SER en prévision de la prochaine période quadriennale.

Activité de recherche

Pendant l'année écoulée, le SAKK a inclus 831 patients dans 41 études cliniques, soit les effectifs les plus élevés enregistrés cette décennie. Parmi ces patients, 481 ont été enrôlés dans des études propres. Au total, onze études SAKK ont été validées par le Comité. En 2009, le SAKK a développé seize études nouvelles, dont six ont déjà été lancées. Quinze travaux rédigés sous la direction du SAKK ou avec son concours décisif ont été publiés.

L'admission de patients a été très satisfaisante pour la plupart des études. Les études de phase II, qui enrôlent rapidement, posent cependant un défi particulier. L'expérience montre que, pour un grand nombre, le recrutement intervient nettement plus vite que prévu. La possibilité de participer à ces études intéresse vivement les centres. Mais une inclusion de patients aussi rapide est difficilement conciliable avec la réalisation d'une analyse intermédiaire, souvent prévue. De plus, les centres qui s'associent à une étude à un stade relativement tardif ne disposent que de peu de temps pour admettre les patients.

La première étude dont les données seront intégralement collectées par notre systéme de saisie électronique des données SINATRAS a été lancée en 2009. En évolution constante, ce système permet d'alléger considérablement le travail occasionné auprès du Centre de coordination et des centres hospitaliers.

La soumission de l'étude SAKK 08/08 a été effectuée conformément au nouveau concept de commission d'éthique dirigeante, dont le groupe de travail des Commissions d'éthique (AGEK) est l'instigatrice. D'ici à fin 2010, le SAKK aura recueilli davantage d'expérience avec cette procédure.

Cours de formation
En 2009, le SAKK a dispensé une formation continue à des médecins investigateurs et a organisé conjointement avec la Clinical Trial Unit (CTU) de Berne un perfectionnement supplémentaire à leur intention. En outre, le service statistique du SAKK s'est associé à l'Institut de biostatistique de l'Université de Zurich pour animer un symposium intitulé « Stopping trials early – good for patients or for sponsors ? ». Suscitant un vif intérêt, toutes ces manifestations ont été bien suivies par les divers groupes professionnels.

Coopérations
Les mutations rapides de la recherche clinique en Suisse placent le SAKK devant la nécessité de se positionner clairement et de défendre ses intérêts. Aussi, pour peser davantage – notamment dans la sphère politique – et sensibiliser un plus large public aux enjeux de la recherche clinique, notre organisation est-elle de plus en plus favorable à des rapprochements avec d'autres groupes.

Une première réunion de travail a eu lieu avec des représentants de la Swiss Clinical Trial Organisation (SCTO). Une volonté partagée de poursuivre la collaboration opérationnelle engagée et de l'approfondir là où cela s'avère judicieux a été exprimée.

Oncosuisse
A l'été 2009, Oncosuisse a été transformée en société simple afin d'être en mesure de se concentrer davantage sur les enjeux politico-stratégiques de la lutte contre le cancer. L'organisation est financée par les cotisations de membres de ses quatre partenaires, à savoir la Recherche suisse contre le cancer, la Ligue suisse contre le cancer, le SAKK et le SPOG. Oncosuisse est présidée par le Pr Richard Herrmann, président du SAKK, et dirigée par le Dr Peter Brauchli, Directeur du SAKK. Ces liens personnels sont sources de synergies.

Le principal projet d'Oncosuisse consiste à concevoir le Programme national contre le cancer (NKP) 2011–2015. Le NKP est un instrument politique coordonné au niveau national qui vise à améliorer la recherche, la prévention, le dépistage précoce et le traitement du cancer ainsi que la gestion des conséquences de la maladie. Activement associé à la préparation de cette nouvelle édition, le SAKK est chargé de l'élaboration des volets Recherche et Traitement.

Centre de coordination
L'année sous revue a été marquée par des vacances temporaires à des fonctions dirigeantes (départs et congés de maternité) et, d'une manière générale, par une insuffisance des ressources et des compétences personnelles au regard du nombre de projets.

Au sein du Centre de coordination du SAKK, l'unité de coordination d'études a été restructurée et divisée en quatre équipes. Rebaptisée « Clinical Trial Management (CTM) », elle est dirigée par Ursula Kühnel. Cette mesure a permis de simplifier les opérations et de délimiter plus clairement les responsabilités.

Afin de faire face au volume croissant d'études à développer et au surcroît de travail qui en découle, l'effectif d'employés fixes du SAKK a été étoffé fin 2009 de neuf personnes (soit 4075 pour cent de postes au total). Un augmentation de l'effectif a été notament nécessaire dans notre domaine d'activité principal (développement et réalisation d'études). La direction de l'équipe Monitoring a été confiée au Dr Céline Genton. La coordination d'études a été rejointe par deux nouvelles responsables d'équipe – le Dr Simona Berardi et Anja Grzesiczek –, qui disposent l'une

comme l'autre d'une expérience de la recherche clinique. A l'instar de l'unité CTM, le service informatique a été développé. En novembre 2009, le Dr Peter Durrer a pris ses fonctions en tant que responsable QA & GCP Compliance, succédant à Doris Lanz. Afin de bénéficier de locaux plus spacieux, les services Informatique, Partner Relations et Regulatory Affairs ont emménagé dans des bureaux nouvellement loués au 60 Effingerstrasse.

Malgré des conditions parfois difficiles, les collaborateurs du Centre de coordination ont fait preuve d'un dévouement exceptionnel. Je remercie vivement les responsables de service et leurs équipes de l'engagement infatigable qu'ils ont montré dans la poursuite des objectifs du SAKK.

Membres du Comité

Président
Pr Richard Herrmann
Universitätsspital Basel

Vize-président
Pr Beat Thürlimann
Kantonsspital St. Gallen

Pr Daniel Betticher
Kantonsspital Freiburg

Pr Stephan Bodis
Kantonsspital Aarau

PD Dr Yves Chalandon
Hôpital Universitaire
de Genève

Pr Martin Fey
Inselspital Bern

Pr Michele Ghielmini
Ospedale Regionale
Lugano

Pr Holger Moch
Universitätsspital Zürich

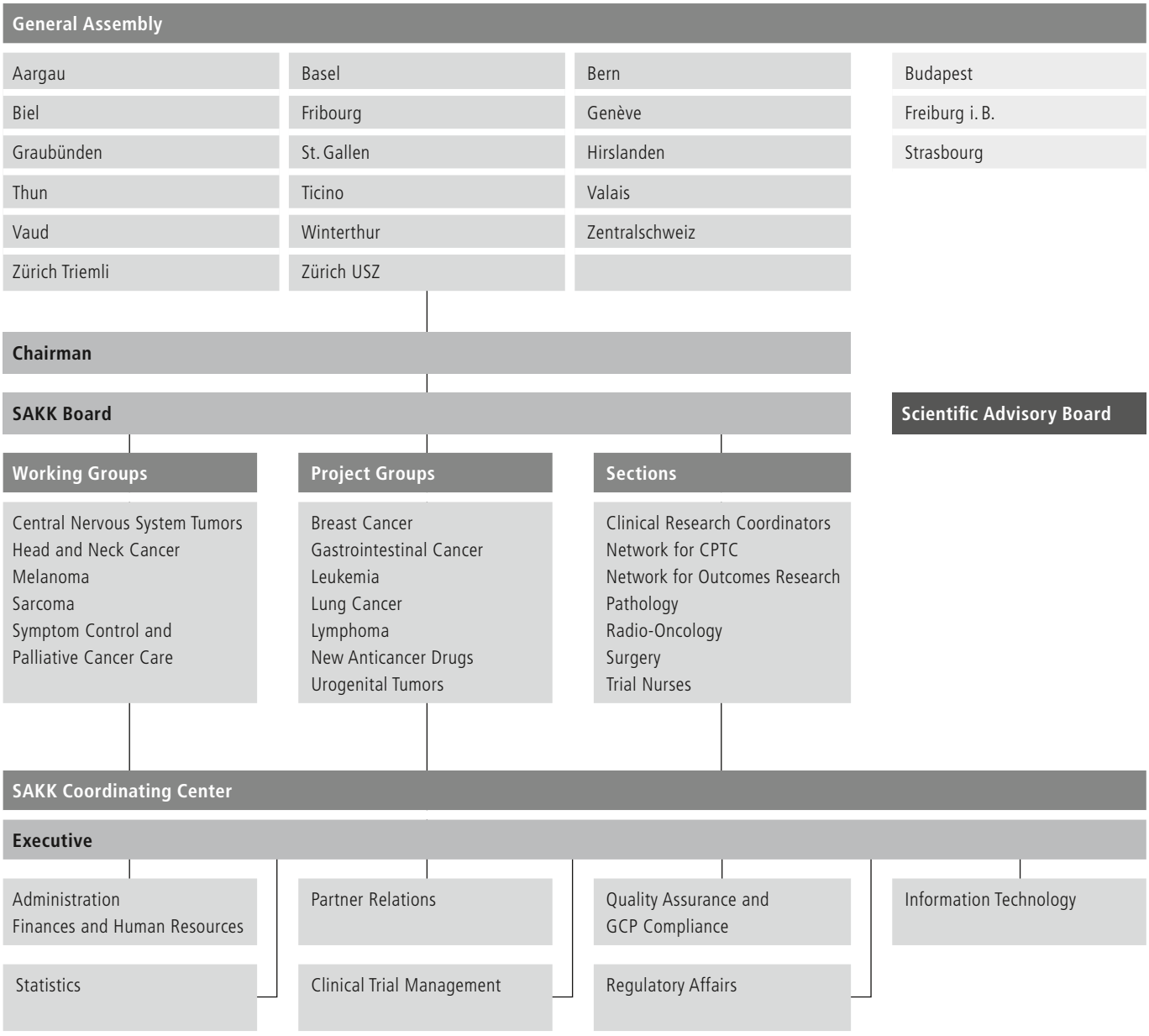
Pr Christoph Renner
Universitätsspital Zürich

PD Dr Arnaud Roth
Hôpital Cantonal
Universitaire Genève

Dr Roger von Moos
Kantonsspital Chur

Pr Walter Richard Marti
Universitätsspital Basel

Organigram Swiss Group for Clinical Cancer Research (SAKK)



Cadres, distinctions, promotions du SAKK

Médecin-chef

– Pr Walter R. Marti, médecin-chef en chirurgie, Hôpital cantonal d'Aarau

Médecins dirigeants

– Dr Christoph Mamot, privat-docent, médecin dirigeant en oncologie, Hôpital cantonal d'Aarau
– Dr Ulrich Mey, privat-docent, médecin dirigeant en oncologie, Hôpital cantonal de Coire
– Pr Bernhard Pestalozzi, médecin dirigeant, Clinique et Policlinique d'oncologie, Hôpital universitaire de Zurich

Privat-docents

– Dr Frank Stenner-Liewen, privat-docent, chef de clinique et de policlinique d'oncologie, Hôpital universitaire de Zurich
– Dr Florian Strasser, privat-docent, chef de clinique d'oncologie et de médecine palliative, Hôpital cantonal de Saint-Gall

Chaires universitaires

– Pr Thomas Pabst, médecin dirigeant à l'Institut d'oncologie médicale, Hôpital de l'Ile, Berne
– Pr Markus Manz, responsable de la clinique d'hématologie de l'Hôpital universitaire de Zurich
– Pr Cristiana Sessa, Institut d'oncologie de la Suisse italienne (IOSI), Hôpital San Giovanni, Bellinzone (professeur titulaire)

Nominations

– Pr Donal Hollywood, responsable de l'Unité académique d'oncologie moléculaire et clinique, Trinity College, Dublin: membre du Conseil scientifique du SAKK (successeur du Pr Michael Baumann)
– Pr Christoph Renner, médecin dirigeant à la Clinique et Policlinique d'oncologie, Hôpital universitaire de Zurich: responsable du secteur Médecine interne
– Pr Beat Thürlimann, médecin-chef au Centre de sénologie de Suisse orientale, Hôpital cantonal de Saint-Gall: président du SAKK à compter du 1er juillet 2010
– Dr Emanuele Zucca, privat-docent, Institut d'oncologie de la Suisse italienne (IOSI), Hôpital San Giovanni, Bellinzone: président du groupe de projet Lymphomes du SAKK (successeur du Dr Nicolas Ketterer, privat-docent)

Lauréats

– Pr Alois Gratwohl, responsable du Service d'hématologie de l'Hôpital universitaire de Bâle: Prix de la Ligue suisse contre le cancer
– Dr Ulrich Güller, privat-docent, professeur adjoint à l'Université de Bâle: Prix Pfizer de la recherche en oncologie 2009
– Dr Viviane Hess, privat-docent, Clinique d'oncologie, Hôpital universitaire de Bâle: Prix Pfizer de la recherche en oncologie 2009 et Prix Marie Heim-Vögtlin du FNS
– Dr Igor Langer, privat-docent, médecin-chef en chirurgie à l'Hôpital cantonal du Bruderholz: Prix Pfizer de la recherche en oncologie 2009
– Pr Adrian Ochsenbein, médecin dirigeant de la Clinique d'oncologie médicale de l'Hôpital de l'Ile, Berne: Bourse de la recherche 2009 d'Amgen
– Dr Alfred Zippelius, privat-docent, Clinique d'oncologie de l'Hôpital universitaire de Bâle: subside Professeur boursier du FNS

Assemblée semestrielle de juin

L'Assemblée semestrielle d'été du SAKK s'est tenue le 18 juin 2009. Elle a réuni plus de 200 spécialistes de l'oncologie, représentants de laboratoires pharmaceutiques et collaborateurs du Centre de coordination du SAKK au Centre de conférences Blumenberg, à Berne. Au cours de séances bien suivies, des membres des groupes de projet, des groupes de travail et des sections du SAKK ont passé en revue les études en cours et à venir dans leurs domaines de recherche respectifs.

Les participants à l'Assemblée des membres du SAKK ont approuvé les comptes annuels du SAKK, donné décharge aux membres du Comité et adopté le nouveau règlement d'organisation, qui définit la structure et les processus du Comité et, dans le souci d'une plus grande transparence, établit l'obligation, pour les membres du Comité comme pour les responsables d'étude, de déclarer leurs conflits d'intérêts potentiels.

Les membres ont par ailleurs élu à l'unanimité comme nouveau membre du Conseil scientifique le Pr Donal Hollywood, oncologue au Trinity College de Dublin, en Irlande. Celui-ci succède au Pr Michael Baumann, de l'Université technique de Dresde.

Donal Hollywood

Le Pr Richard Herrmann, président du SAKK, le Pr Adrian Ochsenbein et le Dr Jan-Henrik Terwey, Amgen

Assemblée semestrielle de novembre

L'Assemblée semestrielle d'hiver du SAKK, qui s'étend sur deux jours, s'est tenue les 26 et 27 novembre 2009 au Centre des congrès de Bâle. Les sessions des divers groupes de recherche du SAKK ont été complétées par le symposium du SAKK ainsi que par un symposium satellite financé par les sociétés PharmaMar et Mundipharma.

Le symposium du SAKK a donné l'occasion au Dr Adrian Wicki et au Dr Christoph Mamot, privat-docent – tous deux lauréats de la bourse de recherche SAKK/Amgen 2007 – de dresser une rétrospective des travaux sur les immunoliposomes qui leur avaient valu la récompense. Dans la foulée, la bourse de recherche SAKK/Amgen 2009, dotée de 50 000 CHF, a été décernée au Dr Adrian Ochsenbein, de l'Hôpital de l'Ile à Berne, pour ses recherches dans le domaine des cellules souches tumorales et de l'immunothérapie.

Après la remise de la récompense au Pr Ochsenbein, le Dr Silvia Ess, du registre des tumeurs de Saint-Gall, et le Pr Beat Thürlimann, de l'Hôpital cantonal de Saint-Gall, ont présenté les résultats de l'étude «Patterns of care of breast cancer in Switzerland», dont les conclusions partiellement controversées sur la prise en charge du cancer du sein et sur le traitement des patients concernés avaient causé d'importants remous en Suisse.

Enfin, l'Assemblée des membres a élu à l'unanimité le Pr Beat Thürlimann, de l'Hôpital cantonal de Saint-Gall, à la présidence du SAKK. Celui-ci succèdera ainsi au Pr Richard Herrmann, qui se retirera en juin 2010 au terme d'un second et dernier mandat possible.

Pr Dr Richard Herrmann

Pr Dr Beat Thürlimann

Octroi du prix SAKK/Pfizer 2010
Le SAKK et Pfizer SA à Zurich-Oerlikon décernent un an sur deux un prix de qualité de la recherche clinique en oncologie. D'un montant de 20 000 CHF, celui-ci sera remis à l'occasion de l'Assemblée semestrielle d'hiver, qui aura lieu le 25 novembre 2010 à Bâle. Toute personne ou équipe qui, en Suisse, se consacre à la recherche clinique en oncologie peut faire acte de candidature en vue de l'obtention du prix.

Le prix récompense des travaux ou des projets qui permettent d'accroître la qualité et la performance de la recherche clinique en oncologie chez les enfants et les adultes en Suisse par le recours à des procédures novatrices propres à améliorer l'organisation des études et/ou la qualité des données, par la mise en jeu d'approches pionnières en matière de recrutement de patients ou par une contribution à la formation, à la formation continue ou au perfectionnement. Il peut s'agir tant de projets achevés ou en cours que de concepts praticables.

La date limite de dépôt des dossiers est fixée au 15 septembre 2010.

Bourse SAKK/Dr Paul Janssen
Le SAKK et Janssen-Cilag SA prévoient d'attribuer une bourse annuelle dotée de 50 000 CHF. Celle-ci vise à permettre à de jeunes médecins de passer quatre mois dans un institut de recherche étranger de renom, où ils pourront améliorer leurs connaissances de la recherche clinique en oncologie et acquérir la maîtrise d'outils nécessaires à la mise en œuvre d'études performantes.

La bourse de formation sera décernée à un rythme annuel au cours des trois prochaines années. Elle est ouverte à des médecins qui exercent dans les hôpitaux de Suisse, suivent une formation en oncologie et ont des liens avec le SAKK. La date limite de dépôt des candidatures est fixée au 1er septembre 2010.

Le président du SAKK, qui présidera le jury, sera chargé de l'examen des candidatures. La bourse sera remise à l'occasion de l'Assemblée semestrielle d'hiver prévue en novembre 2010, sur la base de l'expertise du jury. Les lauréats seront assistés par le SAKK et Janssen-Cilag SA dans le choix d'un institut de recherche adéquat.

Pour vous procurer le règlement de participation relatif à l'un ou l'autre de ces prix ou obtenir des précisions complémentaires, veuillez vous adresser à:

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3008 Berne
Tél. 031 389 93 96
E-mail: stephanie.zuellig@sakk.ch

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

SAKK 16/01 Stupp, R., Mayer, M., Kann, R., Weder, W., Zouhair, A., Betticher, D. C., Roth, A. D., Stahel, R. A., Majno, S. B., Peters, S., Jost, L., Furrer, M., Thierstein, S., Schmid, R. A., Hsu-Schmitz, S. F., Mirimanoff, R. O., Ris, H. B., and Pless, M., *Neoadjuvant chemotherapy and radiotherapy followed by surgery in selected patients with stage IIIB non-small-cell lung cancer: a multicentre phase II trial:* Lancet Oncol, v. 10, p. 785–93.

Breast Cancer

EORTC 10994/BIG 00-01 Farmer, P., Bonnefoi, H., Anderle, P., Cameron, D., Wirapati, P., Becette, V., Andre, S., Piccart, M., Campone, M., Brain, E., Macgrogan, G., Petit, T., Jassem, J., Bibeau, F., Blot, E., Bogaerts, J., Aguet, M., Bergh, J., Iggo, R., and Delorenzi, M., *A stroma-related gene signature predicts resistance to neoadjuvant chemotherapy in breast cancer:* Nat Med, v. 15, p. 68–74.

BIG 1-98 Giobbie-Hurder, A., Price, K. N., and Gelber, R. D., 2009, Design, conduct, and analyses of Breast International Group (BIG) 1-98: *a randomized, double-blind, phase-III study comparing letrozole and tamoxifen as adjuvant endocrine therapy for postmenopausal women with receptor-positive, early breast cancer:* Clin Trials, v. 6, p. 272–87

Mouridsen, H., Giobbie-Hurder, A., Goldhirsch, A., Thurlimann, B., Paridaens, R., Smith, I., Mauriac, L., Forbes, J. F., Price, K. N., Regan, M. M., Gelber, R. D., and Coates, A. S., *Letrozole therapy alone or in sequence with tamoxifen in women with breast cancer:* N Engl J Med, v. 361, p. 766–76.

Rabaglio, M., Sun, Z., Price, K. N., Castiglione-Gertsch, M., Hawle, H., Thurlimann, B., Mouridsen, H., Campone, M., Forbes, J. F., Paridaens, R. J., Colleoni, M., Pienkowski, T., Nogaret, J. M., Lang, I., Smith, I., Gelber, R. D., Goldhirsch, A., and Coates, A. S., *Bone fractures among postmenopausal patients with endocrine-responsive early breast cancer treated with 5 years of letrozole or tamoxifen in the BIG 1-98 trial:* Ann Oncol. 2009 Sep;20(9):1489–98.

ESO Cardoso, F., Bedard, P. L., Winer, E. P., Pagani, O., Senkus-Konefka, E., Fallowfield, L. J., Kyriakides, S., Costa, A., Cufer, T., and Albain, K. S., *International Guidelines for Management of Metastatic Breast Cancer: Combination vs Sequential Single-Agent Chemotherapy:* J Natl Cancer Inst, 101(17):1174–81.

IBSCG Gianni, L., Gelber, S., Ravaioli, A., Price, K. N., Panzini, I., Fantini, M., Castiglione-Gertsch, M., Pagani, O., Simoncini, E., Gelber, R. D., Coates, A. S., and Goldhirsch, A., *Second non-breast primary cancer following adjuvant therapy for early breast cancer: a report from the International Breast Cancer Study Group:* Eur J Cancer, v. 45, p. 561–71.

Pagani, O., Price, K. N., Gelber, R. D., Castiglione-Gertsch, M., Holmberg, S. B., Lindtner, J., Thurlimann, B., Collins, J., Fey, M. F., Coates, A. S., and Goldhirsch, A., *Patterns of recurrence of early breast cancer according to estrogen receptor status: a therapeutic target for a quarter of a century:* Breast Cancer Res Treat. 2009 Sep;117(2):319–24.

IBCSG 11-93 Thurlimann, B., Price, K. N., Gelber, R. D., Holmberg, S. B., Crivellari, D., Colleoni, M., Collins, J., Forbes, J. F., Castiglione-Gertsch, M., Coates, A. S., and Goldhirsch, A., *Is chemotherapy necessary for premenopausal women with lower-risk node-positive, endocrine responsive breast cancer?* 10-year update of International Breast Cancer Study Group Trial 11-93: Breast Cancer Res Treat, v. 113, p. 137–44.

IBCSG 15-95 Colleoni, M., Sun, Z., Martinelli, G., Basser, R. L., Coates, A. S., Gelber, R. D., Green, M. D., Peccatori, F., Cinieri, S., Aebi, S., Viale, G., Price, K. N., and Goldhirsch, A., *The effect of endocrine responsiveness on high-risk breast cancer treated with dose-intensive chemotherapy: results of International Breast Cancer Study Group Trial 15-95 after prolonged follow-up:* Ann Oncol, v. 20, p. 1344–51.

Leukemia

SAKK 32/95 Zenhausern, R., Von Rohr, A., Rufibach, K., Solenthaler, M., Meyer-Monard, S., Gratwohl, A., Hess, U., Bargetzi, M. J., Kovacsovic, T., Leoncini, L., and Tobler, A., *Low dose 2-chlorodeoxyadenosine given as a single subcutaneous injection in patients with hairy cell leukemia: a multicentre trial SAKK 32/95:* Leuk Lymphoma, v. 50, p. 133–6.

SAKK 32/98 Zenhausern, R., Schmitz, S. F., Solenthaler, M., Heim, D., Meyer-Monard, S., Hess, U., Leoncini, L., Bargetzi, M., Rufener, B., and Tobler, A., *Randomized trial of daily versus weekly administration of 2-chlorodeoxyadenosine in patients with hairy cell leukemia: a multicenter phase III trial (SAKK 32/98):* Leuk Lymphoma, 50:1501.

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 2009 online.

Cassinat, B., de Botton, S., Kelaidi, C., Ades, L., Zassadowski, F., Guillemot, I., Schlageter, M. H., Raffoux, E., Harousseau, J. L., Legrand, O., Escoffre-Barbe, M., Reman, O., Gardembas, M., Himberlin, C., Cahn, J. Y., Guyotat, D., Bouscary, D., Parry, A., Rousselot, P., Baruchel, A., Dombret, H., Chevret, S., Fenaux, P., and Chomienne, C., *When can real-time quantitative RT-PCR effectively define molecular*

relapse in acute promyelocytic leukemia patients? (Results of the French Belgian Swiss APL Group): Leuk Res, v. 33, p. 1178–82.

Kelaidi, C., Chevret, S., De Botton, S., Raffoux, E., Guerci, A., Thomas, X., Pigneux, A., Lamy, T., Rigal-Huguet, F., Meyer-Monard, S., Chevallier, P., Maloisel, F., Deconinck, E., Ferrant, A., Fegueux, N., Ifrah, N., Sanz, M., Dombret, H., Fenaux, P., and Ades, L., *Improved Outcome of Acute Promyelocytic Leukemia With High WBC Counts Over the Last 15 Years:* The European APL Group Experience: J Clin Oncol 2009; 27:2668.

CML IV Saussele, S., Lauseker, M., Gratwohl, A., Beelen, D. W., Bunjes, D., Schwerdtfeger, R., Kolb, H. J., Ho, A. D., Falge, C., Holler, E., Schlimok, G., Zander, A. R., Arnold, R., Kanz, L., Dengler, R., Haferlach, C., Schlegelberger, B., Pfirrmann, M., Muller, M. C., Schnittger, S., Leitner, A., Pletsch, N., Hochhaus, A., Hasford, J., and Hehlmann, R., *Allogeneic hematopoietic stem cell transplantation (alloSCT) for chronic myeloid leukemia in the imatinib era; evaluation of its impact within a subgroup of the randomized German CML Study IV:* Blood 2009 online.

GRAALL Familiades, J., Bousquet, M., Lafage-Pochitaloff, M., Bene, M. C., Beldjord, K., De Vos, J., Dastugue, N., Coyaud, E., Struski, S., Quelen, C., Prade-Houdellier, N., Dobbelstein, S., Cayuela, J. M., Soulier, J., Grardel, N., Preudhomme, C., Cave, H., Blanchet, O., Lheritier, V., Delannoy, A., Chalandon, Y., Ifrah, N., Pigneux, A., Brousset, P., Macintyre, E. A., Huguet, F., Dombret, H., Broccardo, C., and Delabesse, E., *PAX5 mutations occur frequently in adult B-cell progenitor acute lymphoblastic leukemia and PAX5 haploinsufficiency is associated with BCR-ABL1 and TCF3-PBX1 fusion genes: a GRAALL study:* Leukemia; 23:1989–98.

GRAALL-2003 Huguet, F., Leguay, T., Raffoux, E., Thomas, X., Beldjord, K., Delabesse, E., Chevallier, P., Buzyn, A., Delannoy, A., Chalandon, Y., Vernant, J. P., Lafage-Pochitaloff, M., Chassevent, A., Lheritier, V., Macintyre, E., Bene, M. C., Ifrah, N., and Dombret, H., *Pediatric-Inspired Therapy in Adults With Philadelphia Chromosome-Negative Acute Lymphoblastic Leukemia:* The GRAALL-2003 Study: J Clin Oncol, 27:911–18.

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., *Adverse prognostic significance of CD20 expression in adults with Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia:* Haematologica 2009 online.

HOVON Lowenberg, B., Ossenkoppele, G. J., van Putten, W., Schouten, H. C., Graux, C., Ferrant, A., Sonneveld, P., Maertens, J., Jongen-Lavrencic, M., von Lilienfeld-Toal, M., Biemond, B. J., Vellenga, E., van Marwijk Kooy, M., Verdonck, L. F., Beck, J., Dohner, H., Gratwohl, A., Pabst, T., and Verhoef, G., *High-dose daunorubicin in older patients with acute myeloid leukemia:* N Engl J Med, v. 361, p. 1235–48.

Head and Neck

SAKK 10/94 Ghadjar, P., Blank-Liss, W., Simcock, M., Hegyi, I., Beer, K. T., Moch, H., Aebersold, D. M., and Zimmer, Y., *MET Y1253D-activating point mutation and development of distant metastasis in advanced head and neck cancers:* Clin Exp Metastasis, 26(7):809–15.

SAKK 10/94 Meta-analysis Michiels, S., Le Maitre, A., Buyse, M., Burzykowski, T., Maillard, E., Bogaerts, J., Vermorken, J. B., Budach, W., Pajak, T. F., Ang, K. K., Bourhis, J., and Pignon, J. P., *Surrogate endpoints for overall survival in locally advanced head and neck cancer: meta-analyses of individual patient data:* Lancet Oncol, v. 10, p. 341–50.

Pignon, J. P., le Maitre, A., Maillard, E., and Bourhis, J., Meta-analysis of chemotherapy in head and neck cancer (MACH-NC): *an update on 93 randomised trials and 17,346 patients:* Radiother Oncol, v. 92, p. 4–14.

Lymphoma

SAKK 35/98 Meta-analysis Vidal, L., Gafter-Gvili, A., Leibovici, L., Dreyling, M., Ghielmini, M., Hsu Schmitz, S. F., Cohen, A., and Shpilberg, O., *Rituximab maintenance for the treatment of patients with follicular lymphoma: systematic review and meta-analysis of randomized trials:* J Natl Cancer Inst, v. 101, p. 248–55.

SAKK 36/03 Hitz, F., Martinelli, G., Zucca, E., von Moos, R., Mingrone, W., Simcock, M., Peterson, J., Cogliatti, S. B., Bertoni, F., Zimmermann, D. R., and Ghielmini, M., *A multicentre phase II trial of gemcitabine for the treatment of patients with newly diagnosed, relapsed or chemotherapy resistant mantle cell lymphoma:* SAKK 36/03: Hematol Oncol, v. 27, p. 154–9.

GHSG Eichenauer, D. A., Bredenfeld, H., Haverkamp, H., Muller, H., Franklin, J., Fuchs, M., Borchmann, P., Muller-Hermelink, H. K., Eich, H. T., Muller, R. P., Diehl, V., and Engert, A., *Hodgkin's lymphoma in adolescents treated with adult protocols: a report from the German Hodgkin study group:* J Clin Oncol, v. 27, p. 6079–85.

Martin-Subero, J. I., Kreuz, M., Bibikova, M., Bentink, S., Ammerpohl, O., Wickham-Garcia, E., Rosolowski, M., Richter, J., Lopez-Serra, L., Ballestar, E., Berger, H., Agirre, X., Bernd, H. W., Calvanese, V., Cogliatti, S. B., Drexler, H. G., Fan, J. B., Fraga, M. F., Hansmann, M. L., Hummel, M., Klapper, W., Korn, B., Kuppers, R., Macleod, R. A., Moller, P., Ott, G., Pott, C., Prosper, F., Rosenwald, A., Schwaenen, C., Schubeler, D., Seifert, M., Sturzenhofecker, B., Weber, M., Wessendorf, S., Loeffler, M., Trumper, L., Stein, H., Spang, R., Esteller, M., Barker, D., Hasenclever, D., and Siebert, R.;

Molecular Mechanisms in Malignant Lymphomas Network Project of the Deutsche Krebshilfe. New insights into the biology and origin of mature aggressive B-cell lymphomas by combined epigenomic, genomic, and transcriptional profiling. Blood 2009,113(11):2488–97.

Barth TF, Bernd HW, Cogliatti SB, Feller AC, Hansmann ML, Hummel M, Klapper W, Möller P, Müller-Hermelink HK, Ott G, Rosenwald A, Stein H, Szcepanowski M, Wacker HH, Behrmann P, Daniel P, Dierlammm J, Haralambieva E, Harder L, Holterhus PM, Küppers R, Kube D, Lichter P, Martín-Subero JI, Murga-Peñas EM, Pott C, Pscherer A, Schwaenen C, Siebert R, Trautmann H, Vockerodt M, Wessendorf S, Bentink S, Berger H, Hasenclever D, Kreuz M, Loeffler M, Rosolowski M, Spang R, Stürzenhofecker B, Trümper L, Wehner M., *New insights into the biology and origin of mature aggressive B-cell lymphomas by combined epigenomic, genomic, and transcriptional profiling, Supplemental Data:* Blood, v. 113, p. 2488–97.

GHSG-HD 9 Engert, A., Diehl, V., Franklin, J., Lohri, A., Dorken, B., Ludwig, W. D., Koch, P., Hanel, M., Pfreundschuh, M., Wilhelm, M., Trumper, L., Aulitzky, W. E., Bentz, M., Rummel, M., Sezer, O., Muller-Hermelink, H. K., Hasenclever, D., and Loffler, M., *Escalated-dose BEACOPP in the treatment of patients with advanced-stage Hodgkin's lymphoma: 10 years of follow-up of the GHSG HD9 study:* J Clin Oncol, v. 27, p. 4548–54.

IFM 99-02 and IFM 99-04 Harousseau, J. L., Avet-Loiseau, H., Attal, M., Charbonnel, C., Garban, F., Hulin, C., Michallet, M., Facon, T., Garderet, L., Marit, G., Ketterer, N., Lamy, T., Voillat, L., Guilhot, F., Doyen, C., Mathiot, C., and Moreau, P., *Achievement of at least very good partial response is a simple and robust prognostic factor in patients with multiple myeloma treated with high-dose therapy: long-term analysis of the IFM 99-02 and 99-04 Trials:* J Clin Oncol, v. 27, p. 5720–6.

RICOVER-60 Boehme, V., Schmitz, N., Zeynalova, S., Loeffler, M., and Pfreundschuh, M., *2009, CNS events in elderly patients with aggressive lymphoma treated with modern chemotherapy (CHOP-14) with or without rituximab: an analysis of patients treated in the RICOVER-60 trial of the German High-Grade Non-Hodgkin Lymphoma Study Group (DSHNHL):* Blood, v. 113, p. 3896–902.

Bernd HW, Ziepert M, Thorns C, Klapper W, Wacker HH, Hummel M, Stein H, Hansmann ML, Ott G, Rosenwald A, Müller-Hermelink HK, Barth TF, Möller P, Cogliatti SB, Pfreundschuh M, Schmitz N, Trümper L, Höller S, Löffler M, Feller AC; *German High Grade Non-Hodgkin's Lymphoma Study Group (DSHNHL), Loss of HLA-DR expression and immunoblastic morphology predict adverse outcome in diffuse large B-cell lymphoma - analyses of cases from two prospective randomized clinical trials.* Haematologica, 94(11):1569–80.

Gastrointestinal Cancers

SAKK 40/93 Herrmann, R., Lorenz, M., Zuber, M., Rufibach, K., and Laffer, U., *Perioperative and adjuvant chemotherapy in colon cancer: results of SAKK trial 40/93:* Int J Colorectal Dis, v. 24, p. 351–2.

SAKK 44/00 Meta-analysis Cunningham, D., Chau, I., Stocken, D. D., Valle, J. W., Smith, D., Steward, W., Harper, P. G., Dunn, J., Tudur-Smith, C., West, J., Falk, S., Crellin, A., Adab, F., Thompson, J., Leonard, P., Ostrowski, J., Eatock, M., Scheithauer, W., Herrmann, R., and Neoptolemos, J. P., *Phase III randomized comparison of gemcitabine versus gemcitabine plus capecitabine in patients with advanced pancreatic cancer:* J Clin Oncol, v. 27, p. 5513–8.

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., *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, 28(3):466–74. Epub 2009 Dec 14.

Bosman, F. T., Yan, P., Tejpar, S., Fiocca, R., Van Cutsem, E., Kennedy, R. D., Dietrich, D., and Roth, A., *Tissue Biomarker Development in a Multicentre Trial Context: a Feasibility Study on the PETACC3 Stage II and III Colon Cancer Adjuvant Treatment Trial:* Clin Cancer Res,15(17):5528–33.

SAKK 75/02 Klaeser, B., Nitzsche, E., Schuller, J. C., Koberle, D., Widmer, L., Balmer-Majno, S., Hany, T., Cescato-Wenger, C., Brauchli, P., Zund, M., Pestalozzi, B. C., Caspar, C., Albrecht, S., von Moos, R., and Ruhstaller, T., *Limited predictive value of FDG-PET for response assessment in the preoperative treatment of esophageal cancer: results of a prospective multi-center trial (SAKK 75/02):* Onkologie, v. 32, p. 724–30.

Ribi, K., Koeberle, D., Schuller, J. C., Honegger, H., Roth, A., Hess, V., Moosmann, P., von Moos, R., Borner, M., Lombriser, N., Pestalozzi, B., and Ruhstaller, T., *Is a change in patient-reported dysphagia after induction chemotherapy in locally advanced esophageal cancer a predictive factor for pathological response to neoadjuvant chemoradiation?* Support Care Cancer, 2009 Feb 7.

Ruhstaller, T., Widmer, L., Schuller, J. C., Roth, A., Hess, V., Mingrone, W., von Moos, R., Borner, M., Pestalozzi, B. C., Balmermajno, S., Koberle, D., Terraciano, L., Schnider, A., Bodis, S., and Popescu, R., *Multicenter phase II trial of preoperative induction chemotherapy followed by chemoradiation with docetaxel and cisplatin for locally advanced esophageal carcinoma (SAKK 75/02):* Ann Oncol, (9):1522–8.

ESPAC-1 Carter, R., Stocken, D. D., Ghaneh, P., Bramhall, S. R., Olah, A., Kelemen, D., Bassi, C., Friess, H., Dervenis, C., Spry, N., Buchler, M. W., and Neoptolemos, J. P., *Longitudinal quality of life data can provide insights on the impact of*

adjuvant treatment for pancreatic cancer-Subset analysis of the ESPAC-1 data: Int J Cancer, v. 124, p. 2960–2965.

Neoptolemos, J. P., Stocken, D. D., Tudur Smith, C., Bassi, C., Ghaneh, P., Owen, E., Moore, M., Padbury, R., Doi, R., Smith, D., and Buchler, M. W., *Adjuvant 5-fluorouracil and folinic acid vs observation for pancreatic cancer: composite data from the ESPAC-1 and -3(v1) trials:* Br J Cancer, v. 100, p. 246–50.

Melanoma

EORTC 18991 Bottomley, A., Coens, C., Suciu, S., Santinami, M., Kruit, W., Testori, A., Marsden, J., Punt, C., Sales, F., Gore, M., Mackie, R., Kusic, Z., Dummer, R., Patel, P., Schadendorf, D., Spatz, A., Keilholz, U., and Eggermont, A., *Adjuvant Therapy With Pegylated Interferon Alfa-2b Versus Observation in Resected Stage III Melanoma: A Phase III Randomized Controlled Trial of Health-Related Quality of Life and Symptoms by the European Organisation for Research and Treatment of Cancer Melanoma Group:* J Clin Oncol, 27(18):2916–23.

Central Nervous System

EORTC 26981/22981-NCIC Stupp, R., Hegi, M. E., Mason, W. P., van den Bent, M. J., Taphoorn, M. J., Janzer, R. C., Ludwin, S. K., Allgeier, A., Fisher, B., Belanger, K., Hau, P., Brandes, A. A., Gijtenbeek, J., Marosi, C., Vecht, C. J., Mokhtari, K., Wesseling, P., Villa, S., Eisenhauer, E., Gorlia, T., Weller, M., Lacombe, D., Cairncross, J. G., and Mirimanoff, R. O., *Effects of radiotherapy with concomitant and adjuvant temozolomide versus radiotherapy alone on survival in glioblastoma in a randomised phase III study: 5-year analysis of the EORTC-NCIC trial:* Lancet Oncol, 10(5):459–66.

Uyl-de Groot, C. A., Stupp, R., and van der Bent, M., *Cost-effectiveness of temozolomide for the treatment of newly diagnosed glioblastoma multiforme:* Expert Rev Pharmacoecon Outcomes Res, v. 9, p. 235–41.

Outcomes Research

Dedes, K. J., Matter-Walstra, K., Schwenkglenks, M., Pestalozzi, B. C., Fink, D., Brauchli, P., and Szucs, T. D., *Bevacizumab in combination with paclitaxel for HER-2 negative metastatic breast cancer: an economic evaluation:* Eur J Cancer, v. 45, p. 1397–406.

Cancer Predisposition Testing and Counseling

Mai, P. L., Friedlander, M., Tucker, K., Phillips, K. A., Hogg, D., Jewett, M. A., Lohynska, R., Daugaard, G., Richard, S., Bonaiti-Pellie, C., Heidenreich, A., Albers, P., Bodrogi, I., Geczi, L., Olah, E., Daly, P. A., Guilford, P., Fossa, S. D., Heimdal, K., Liubchenko, L., Tjulandin, S. A., Stoll, H., Weber, W., Easton, D. F., Dudakia, D., Huddart, R., Stratton, M. R., Einhorn, L., Korde, L., Nathanson, K. L., Bishop, D. T., Rapley, E. A., and Greene, M. H., *The International Testicular Cancer Linkage Consortium: A clinicopathologic descriptive analysis of 461 familial malignant testicular germ cell tumor kindred:* Urol Oncol, 2009 Jan 20.

Eeles RA, Kote-Jarai Z, Al Olama AA, Giles GG, Guy M, Severi G, Muir K, Hopper JL, Henderson B, Haiman C, Schleutker J, Hamdy FC, Neal DE, Donovan JL, Stanford JL, Ostrander EA, Ingles SA, John EM, Thibodeau S, Schaid D, Park J, Spurdle A, Clements J, Dickinson J, Maier C, Vogel W, Dörk T, Rebbeck T, Cooney K, Cannon-Albright L, Chappuis PO, Hutter P, Zeegers M, Kaneva R, Zhang H, Lu YJ, Foulkes WD, English DR, Leongamornlert DA, Tymrakiewicz M, Morrison J, Ardern-Jones AT, Hall AL, O'Brien LT, Wilkinson RA, Page E, Sawyer E, Edwards SM, Dearnaley DP, Saunders E, Horwich A, Huddart RA, Khoo VS, Parker CC, Van As N, Woodhouse CJ, Thompson A, Christmas T, Ogden C, Cooper CS, Southey MC, Smith C, Bagnato M, Lophatananon A, Liu JF, Collbs H, Wahlfors T, Tammela TL, Lewis S, Cox A, Salinas CA, Koopmeiners JS, Karyadi DM, Johanneson B, Stern MC, Corral R, Joshi AD, Shahabi A, McDonnell SK, Collbs P, Steginga S, Batra J, Nelson C, O'Mara T, FitzGerald L, Schürmann P, Meyer A, Kuefer R, Stefflova K, Farnham J, Khan H, Mitkova A, *The UK Genetic Prostate Cancer Study Collaborators/British Association of Urological Surgeons' Section of Oncology, The UK ProtecT Study Collaborators, The PRACTICAL Consortium, Easton DF. Identification of seven new prostate cancer susceptibility loci through a genome-wide association study.* Nat Genet, 41:1116–21.

Consulting by the SAKK CC statistics unit

Ares, C., Hug, E. B., Lomax, A. J., Bolsi, A., Timmermann, B., Rutz, H. P., Schuller, J. C., Pedroni, E., and Goitein, G., *Effectiveness and Safety of Spot Scanning Proton Radiation Therapy for Chordomas and Chondrosarcomas of the Skull Base:* First Long-Term Report: Int J Radiat Oncol Biol Phys, 75(4):1111–8.

Ghadjar, P., Schreiber-Facklam, H., Grater, R., Evers, C., Simcock, M., Geretschlager, A., Blumstein, N. M., Zbaren, P., Zimmer, Y., Wilkens, L., and Aebersold, D. M., *Quantitative Analysis of Extracapsular Extension of Metastatic Lymph Nodes and Its Significance in Radiotherapy Planning in Head and Neck Squamous Cell Carcinoma:* Int J Radiat Oncol Biol Phys, 2009 Jul 31.

Langer, I., Guller, U., Hsu-Schmitz, S. F., Ladewig, A., Viehl, C. T., Moch, H., Wight, E., Harder, F., Oertli, D., and Zuber, M., *Sentinel lymph node biopsy is associated with improved survival compared to level I & II axillary lymph node dissection in node negative breast cancer patients:* Eur J Surg Oncol, v. 35, p. 805–13.

Ruhstaller, T., von Moos, R., Rufibach, K., Ribi, K., Glaus, A., Spaeti, B., Koeberle, D., Mueller, U., Hoefliger, M., Hess, D., Boehme, C., and Thuerlimann, B., *Breast cancer patients on endocrine therapy reveal more symptoms when self-reporting than in pivotal trials: an outcome research study:* Oncology, v. 76, p. 142–8.

Strasser, F., Muller-Kaser, I., and Dietrich, D., *Evaluating cognitive, emotional, and physical fatigue domains in daily practice by single-item questions in patients with advanced cancer: a cross-sectional pragmatic study:* J Pain Symptom Manage, v. 38, p. 505–14.

Other SAKK

Schuller, J. C., *Statistik in der Onkologie. Chancen und Gefahren:* Schweizer Medical Forum, v. 9, p. 192–194.

Schuller, J. C., Mayer, M., Lanz, D., Hsu Schmitz, S.-F., Brauchli, P., Leupin, N., *A novel diagram and complement to the CONSORT chart for presenting multimodal clinical trials:* Contemp Clin Trials, (3):201–4.

Résultats de l'exercice allant du 1er janvier au 31 décembre (en CHF)	**2009**	**2008**
Produit d'exploitation		
Contributions à la recherche SER[1]	4 019 850.00	3 930 520.00
Contributions à la recherche divers[2]	803 600.00	823 410.58
Contributions à la recherche santésuisse	717 062.00	604 384.00
Recettes issues de la coopération avec l'industrie	4 126 604.45	2 268 112.60
Recettes issues de la coopération avec des groupes de recherche étrangers	89 910.11	0.00
Recettes issues du Bulletin Suisse du Cancer	326 490.00	281 885.00
Dons, Legs & Héritages	57 569.80	40 720.00
Recettes diverses	287 745.52	484 918.85
Total produit d'exploitation	**10 428 831.88**	**8 433 951.03**
Charges d'exploitation		
Frais divers liés aux études	– 824 010.07	– 529 278.75
Contributions à la recherche IBCSG[3]	– 250 000.00	– 250 000.00
Contributions à la recherche dans les centres	– 3 009 964.17	– 2 699 123.95
Frais de déplacement, de représentation	– 167 700.44	– 241 480.75
Autres charges d'exploitation	– 192 479.10	– 63 649.62
Total produit d'exploitation	**– 4 444 153.78**	**– 3 783 533.07**
Résultat intermédiaire 1	5 984 678.10	4 650 417.96
Frais de coordination		
Frais de personnel	– 5 016 747.44	– 4 080 476.39
Autres frais de coordination	– 1 042 005.77	– 831 077.70
Total frais de coordination	**– 6 058 753.21**	**– 4 911 554.09**
Résultat intermédiaire 2	– 74 075.11	261 136.13
Résultat financier		
Produits financiers	18 536.98	131 068.35
Charges financières	– 4 695.73	– 117 838.11
Total résultat financier	**13 841.25**	**13 230.24**
Résultat intermédiaire 3	– 60 233.86	– 247 905.89
Variantions de fonds		
Dissolution de provisions	3 133.00	154 628.40
Dissolution de fonds	30 568.00	0.00
Total variantions de fonds	**33 701.00**	154 628.40
Résultat intermédiaire 4	– 26 532.86	– 93 277.49
Résultat exceptionnel et hors exploitation		
Recettes hors période comptable	19 736.66	58 024.39
Dissolution de provisions qui ne sont plus nécessaires	– 126 850.80	0.00
Total résultat exceptionnel et hors exploitation	**– 107 114.14**	58 024.39
Résultat de l'association	**– 133 647.00**	**– 35 253.10**

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