

influence colon and or breast cancer risk and development will inform us not only about biological plausibility for the observed association, but also provide evidence for causality, and be important for practical guidelines both in prevention and importantly also for patients. Proposed biomarkers for the associations between energy imbalance and colon and breast cancer are i.e. genetic susceptibility, steroid hormones, hypersinsulemia, insulin resistance, leptin, increased inflammation: i.e. C-reactive protein, depressed immune function, oxidative stress and DNA repair. Results from recent observational studies and cancer prevention intervention trials will be focused. Finally, some results from those few randomized controlled trials including physical activity among breast and colon cancer patients will be presented.

## Special Session (Sun, 25 Sep, 13:15–14:15) Tips and Tricks to be the Best

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### Middle Face Microvascular Reconstructions Based on Cordeiro Classification

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Middle face reconstructions are usually very difficult. In the reconstruction of this area we can use both artificial materials and autologous tissue, or a combination of these two. In most of the cases a free tissue transfer is used for the coverage. Each defect in this area is unique, and each must be treated individually, but thanks to Cordeiro classification we can apply a protocol of useful microvascular techniques which will provide optimal postoperative outcome in given defect's type. This presentation describes microvascular techniques in a reconstruction of middle face defects' (Type I-IV). A quality of life evaluation based on own modification of University of Washington QOL form is also described. The most important conclusion? – Proper preoperative planning and free flap(s) choice are crucial to obtain satisfactory aesthetic and functional outcome.

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### Tips and Tricks How to be the Best – Clinical Oncologist

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There are several aspects in Medical Oncology in which physicians can be successful; patient care, teaching, and research. With respect to research, several parameters can be used to measure someone's success such as number of publications, impact factor of journals in which manuscripts are published, number of citations, oral presentations, grants awarded, appointments and several others.

As holds true for every aspect of life, success in research is a combination of own capacities and opportunities from which several can be influenced, but others not. Furthermore, opportunities to become successful in research will differ per country, institute and department.

In this presentation, a personal view on how to be successful in cancer research as a clinical oncologist will be given.

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### Radiation Oncologist

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To successfully perform clinical work, research and teaching is often a challenging task. Working as a clinician scientist and university lecturer I will report my experiences and techniques to cope with this challenge. A personal view on for example how to combine experimental research with clinical duties, the impact of mentors and the use of having a fellowship abroad will be discussed.

## Special Session (Sun, 25 Sep, 13:15–14:15) The European Network for Cancer Research in Children and Adolescents (ENCCA) FP7 Project

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### The European Network for Cancer Research in Children and Adolescents(ENCCA) FP7 Project

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ENCCA is a 'Network of Excellence', funded by the European Union's FP7 Programme under the health topic 'Structuring clinical research in paediatric and adolescent oncology in Europe'. The ENCCA consortium is composed of 33 partners from across Europe, including research institutes and organisations recognised as being at the forefront of excellence in paediatric oncology.

The objective is to reduce knowledge fragmentation and enhance their communication, collaboration and management in an effort to advance clinical research in Europe. ENCCA will restructure knowledge-sharing through the integration of the whole chain of stakeholders from the European paediatric oncology community bringing together their expertise and viewpoints to ensure that ENCCA is all-encompassing but remaining patient-centred. Ultimately ENCCA aims to create a sustainable 'European Virtual Institute' to serve as future platform for clinical and translational research in childhood and adolescent cancers in Europe.

The ENCCA consortium is dedicated to

1. Promoting innovative methodologies and designs for clinical trials
2. Harmonising therapeutic strategies by enabling better access to innovative therapies, knowledge and technology in the field of paediatric tumour biology
3. Improving substantially the quality of life of children and adolescents with cancer with a particular emphasis on long term treatments side effects
4. Proposing common ethical definitions, monitor ethical issues present in the implementation of the European clinical research agenda
5. Providing a comprehensive education and training programme, enhancing research mobility, sustainable clinical trial design, training coordination and information to benefit patients' families.

To achieve the ultimate goal of becoming the 'stepping stone' towards an interactive and sustainable European Institute, the ENCCA network will deliver over the next 4 years 18 work packages with a total of 80 milestones and 82 deliverables, streamlined through 3 main channels of activities embracing all tumours groups: Integrated Activities, Joint Research Activities and Spread of Excellence.

The ENCCA consortium envisions a dynamic and open network that can benefit the entire paediatric oncology community in Europe to overcome also current major hurdles like difficulties to run investigator driven clinical trials within the 2004 clinical trial directive and the extremely poor access to new drugs despite the 2007 Paediatric Medicine Regulation.

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### 'Spread of Excellence' (Dissemination) Activities of the European Network of Excellence for Cancer Research in Children and Adolescents (ENCCA)

K. Pritchard-Jones<sup>1</sup>. <sup>1</sup>University College London, Institute of Child Health, London, United Kingdom

Good communication, sharing of knowledge and international coordination of research into paediatric cancer underpins continued advances in this field which are sorely needed. Cancer in children remains a significant public health issue as some 15,000 new cases are diagnosed every year in Europe. Although 80% of cases are cured by multidisciplinary treatments, still 3,000 cases will not survive. The ENCCA network aims to improve the current situation by reducing as far as possible the existing hurdles and pitfalls in paediatric oncology. ENCCA's ultimate goal is to build a sustainable virtual European institute to serve cancer research in children and adolescents for the next decades, including coordinating training opportunities for clinical and non-clinical researchers to significantly improve cure rates and quality of cure for patients.

The 'Spread of Excellence' work packages include disseminating the work of ENCCA to patients, parents, academic researchers and industry to improve partnerships and knowledge of opportunities for participation in clinical trials, research training and collaboration. A specific work

package addresses ethical issues related to the participation of children and adolescents with cancer in clinical research. Concretely, ENCCA will set up very specialized advanced training courses to support integrating biology research into clinical trials, cancer registry training, definition and improvement of cancer pathways, promotion of standards of care. In addition, as the 'Teenagers and Young Adults with Cancer' age group (TYAC) have lower entry rates into clinical trials than younger children, ENCCA will address the issue of improved access to care for (TYAC) to promote cancer awareness at various levels and ensure timely diagnosis for children and adolescents with cancer. This scheme will focus specifically on reaching out to less advantaged areas, promoting healthy lifestyles for survivors of childhood cancers and improving patients' access to 'standard of care' through dissemination of guidelines and referral schemes. In relation to therapeutic advances, ENCCA aims to raise awareness about the needs of paediatric oncology with industry, regulators and parents/patients – a specific work package aims to bring all three to the table with the academic community to promote biology-driven drug development that should lead to safer and more effective therapies for children and adolescents with cancer.

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#### Joint Research Activities of ENCCA FP7 Project

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The 'Joint Research Activities' in ENCCA cover critical research areas in paediatric oncology with the perspective to harmonise and integrate clinical platforms and to create a test-ground for optimised clinical research. Specifically, the following issues will be addressed: early evaluation and prioritisation of new anticancer drugs; improved therapeutic strategies based on predictive biomarkers in leukaemias; risk adaptation of therapy using prognostic biomarkers in malignant solid tumours; clinical epidemiology and prospective registries for patients on standardised protocols; clinical research through registries and sampling in very rare tumours; quality of survivorship.

Advances in paediatric oncology research require the facilitation and capacity to evaluate new anti-cancer compounds in phase I and II trials in children with malignancies in Europe. Prioritisation of compounds to be studied in children will be based on tumour biology and target validation. Thus, a new strategy for drug development in the different paediatric malignancies will be established with EMA and the paediatric committee (PDCO) to arrive at common guidelines. Refractory childhood leukaemias require more refined approaches using predictive biomarkers. Comprehensive standardised diagnostic approaches as well as biobanking will establish a common pipeline for molecular diagnostics in a European virtual laboratory on leukaemias. Neuroblastoma is biologically one of the most intriguing malignancies in childhood as survival may vary drastically from very poor despite intensive treatments to excellent with little or no treatment. Medulloblastoma is the most common brain tumour in childhood treated with surgical resection followed by chemotherapy and radiotherapy. While combined modality treatment has substantially improved the cure rate in both tumour types, survivors suffer from long-term toxic side-effects. For better risk adaptation of therapy in these tumours methodological and logistic standards will be established to implement quality-controlled biological and imaging-defined risk factors for cure without sequelae. Moreover, robust mechanisms for collection of a standardised 'enhanced' dataset through population-based cancer registries or record linkage approaches for all tumour types will be set up. ENCCA also aims at clinical research for very rare tumours (<50 patients/year in >150 centres in Europe) to achieve widespread quality of care for children with rare tumours. Hepatoblastoma will be used as a template for international clinical research for very rare childhood cancers. Finally, quality of survivorship issues in children and adolescents treated for high-risk cancer (focus on medulloblastoma) will be addressed with the ultimate goal that each cancer survivor will have access to a document (Survivorship Passport) summarizing diagnosis and treatment history.

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#### Spread of Excellence Activities of ENCCA

G. Vassal<sup>1</sup>. ENCCA Activity Coordinator, Institut Gustave Roussy, France

The 'Integrated activities' channel covers all paediatric oncology critical infrastructure areas with a view to setting standards and creating a common hosting structure for a sustainable integration for clinical trials, providing easier access to innovative methodology designs with innovative endpoints, facilitating integration of biological data to streamline new drug development and implementing biology guided therapeutic strategies as well as long-term solutions for better cross-platform collaboration. A European sustainable strategy for paediatric oncology clinical trials will

be established to provide accelerated answers for children with cancers. Important issues such as network strategy definition, financial issues, clinical trial cost-effectiveness as well as equipment integration aspects will be addressed. Moreover, a virtual information portal will be set up in the form of a secure communication portal for partners to communicate easily and have access to real-time and full-scale access to knowledge so as to overcome geographical remoteness. Besides, a common scientific data policy will also be established along with data exchange of DICOM images for clinical trials reviews. In addition, the facilitation of clinical trials scheme will present the needs for early drug development studies (Phase I/II) supported by industry or driven by academia as well as investigator-driven Phase III/IV clinical trials. The objective here is to increase the implementation efficiency of pan-European multinational research by agreeing and adopting standardised risk approaches, clinical trial templates and standardised datasets, reducing duplication of efforts and agreeing on a standard definition for an investigational Medical product (IMP). Besides this, issues related to 'biology to guide innovative targeted therapy development' will be addressed with a view to integrating and harmonising existing biological datasets and experimental data allowing for therapy choice guided by biology and innovation to improve treatment outcome for children and adolescents with cancer. Analytical tools will be developed to support this. Moreover, a standardised and innovative methodology for clinical trial design and analysis will be developed in the 'virtual office' by interlinking biostatisticians together. The objective is to ultimately enhance the network expertise in methodology, design and analysis of paediatric clinical studies. Finally, a platform for bone sarcoma trials (phase II-IV) with integrated biology tumour research questions will be established.

### Special Session (Sun, 25 Sep, 13:15–14:15) Assessment of Novel Oncotechnologies

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#### Role for Health Technology Agencies in Assessment of New Cancer Technologies

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**Background:** Canada's federal, provincial and territorial health care decision makers use the Canadian Agency for Drugs and Technologies in Health (CADTH) for credible, impartial advice and evidence-based information about the effectiveness of drugs and other health technologies. CADTH helps inform a variety of decisions by providing a variety of products including rapid responses, formulary drug recommendations, health technology assessments, and optimal use products.

**Material and Methods:** Canadian health care decision makers access CADTH directly or through liaison officers. Their questions are refined and products are scoped to be timely, and relevant to the specific customer's policy or purchasing questions. Relevant literature is typically identified through a peer-reviewed literature search of more than one database; the number and selection depend on the topic. Grey literature is searched from web sites like Health Technology Agencies and professional organizations. Reports may focus on clinical effectiveness, economic effectiveness, or other components like ethical, legal, and psychosocial aspects of a health technology. Peer-review may or may not be required and some work requires panels of experts and public members to develop guidance. Final products are publically available through the CADTH web site.

**Results:** Three reports that CADTH has published on new cancer non-drug technologies include: a rapid systematic review and guidance that informed a province's purchase and use of 1.5 T MRI and 3.0 T MRI scanners for various patient indications including cancer; a rapid systematic review of the comparative clinical and cost-effectiveness of TomoTherapy, GammaKnife, or CyberKnife that was consulted by a provincial cancer agency; and, a summary of evidence regarding high intensity frequency ultrasound for prostate cancer that was used to support the use in practice.

**Conclusions:** Health Technology Agencies like CADTH have an important role in health care decision-making as they deliver syntheses and critical appraisals of the evidence that are timely, relevant, reliable, and impartial. CADTH products inform health care decision makers on the clinical benefit and cost effectiveness of health care technologies, including new cancer technologies.

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#### Randomized Controlled Trials in Assessment of Oncotechnologies

Abstract not received