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-tem 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

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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 (Phasel/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