European Organisation for Research and Treatment of Cancer
Dr Denis Lacombe, Director of the European Organisation for Research and Treatment of Cancer, discusses the organisation’s multidisciplinary work towards improving cancer clinical trials

The European Organisation for Research and Treatment of Cancer (EORTC) celebrated its 50th Anniversary in 2012. Could you outline the organisation’s key aims and how they have changed since its inception?

The EORTC was founded in 1962, and the strength and sustainability of this organisation reside in the simple fact that its mission and aim have remained unchanged. The organisation was set up to combine efforts at the European level to improve the treatment of cancer patients, increase survival and address quality of life. This means, however, the manner in which the organisation reaches its goals has changed and evolved substantially over the last 52 years.

Two traits central to the EORTC have been a multidisciplinary and international approach to cancer clinical research, and today, the strategy of the organisation evolves upon these two essential pillars. Despite a rapidly evolving clinical research landscape due to the complexity of regulatory frameworks, the profusion of newly created national/tumour-based groups and growing economic constraints, the EORTC not only remains unrivalled in Europe, but also contributes significantly to the global cancer research agenda by achieving what can only be accomplished by optimal international collaboration.

In 2014, the EORTC is positioned as an invaluable pan-European clinical and translational research infrastructure. It is a multifaceted organisation that interacts on a daily basis with many stakeholders from patient advocacy groups and pharmaceutical, biotechnology and diagnostic companies to representatives from governments, regulators and payers.

How important are multidisciplinary approaches to the EORTC’s mission?

The empirical approach of comparing treatment A versus treatment B is over. New technologies are now available that help us understand the biology of cancer as well as patterns of resistance. However, this requires complex clinical trials with access to biological material and functional/dynamic imaging so we can gain insight into the mechanisms of action that treatments have on the biology, how tumours react to these treatments and how different treatments could be used together, in sequence, and in which order. Empirically designed trials cannot provide us with these answers. We need to revamp the clinical research process in a way that clinical trials designed to learn can generate the information needed for downstream clinical trials designed to conclude.

In essence, the forms and methods of clinical trials are no longer the same. Multidisciplinary clinical trials – which in the past were limited to surgeons, radiation oncologists and medical oncologists – are now extended to include pathologists, molecular biologists and imaging specialists. Bioinformaticians are also critical in combining and comprehending the resulting complex datasets that lead towards optimal treatment decisions. Such a new form of clinical research requires solid infrastructures that lay the foundation for interactive, multidisciplinary collaboration. Complex trials can then be built using this network and may help the community to control attrition rates and optimise drug development.

How do these multidisciplinary approaches join academics and industry members? Why is this relationship important?

The skills of various stakeholders are needed to conduct these trials, and these skills need to be assembled within a new model of collaboration between industry and academia. We have been working towards fulfilling an urgent need to develop new models of partnership between this pair for early-stage cancer clinical trials. Such optimised early-drug clinical trials could serve as stepping stones to biologically driven late stage trials, avoid many current pitfalls and reduce the high attrition rate of prospective drugs.

In order to realise this, an ‘honest broker’ is needed to ensure the transparency and sustainability within these multiple stakeholder partnerships. Large international academic research organisations are well suited to assume the role by means of their working principles and organisational mission.

What are the main challenges in developing novel treatments for cancer patients? How will identifying subsets of patients with a specific molecular profile help to overcome these challenges?

Personalised medicine faces multiple challenges such as the need to co-develop a new agent with its relevant biomarker or the ability to access efficiently a subset of patients to apply the right technology and methodology to achieve reliable results and control the attrition rate. There are uncoordinated efforts with separate trials hoping to access quite possibly the same patients in the same hospitals. Therefore, we proposed ‘Screening Patients for Efficient Clinical Trial Access’ (SPECTA) as a collaborative screening effort. It provides a single entry for screening and does not omit patients whose tumour unfortunately does not express a given biomarker for a particular trial. Rather, SPECTA can rapidly sort these patients to other treatments. Furthermore, patients can be followed longitudinally throughout the course of their disease and this can increase opportunities to understand the patterns of resistance.

Who are the key stakeholders in the SPECTA programme, and what are the specific benefits for each of them?

To answer this question, we must look at how SPECTA integrates the various partners. First, there is streamlined operational access for patients and their treating physicians to tailored clinical trials. SPECTA maximises access to trials and new drugs, allowing more personalised treatments.
SPECTA is a unique multidisciplinary and multi-stakeholder programme to improve the development of personalised medicine and establish foundations for new healthcare delivery models. It is developed based on regulatory compliant quality assurance processes through which documented biomarkers or emerging biomarkers can be efficiently assessed. It integrates systematic and centralised next-generation sequencing.

**SPECTApath** – across tumours, the challenges of biobanking, qualification, validation of biomarkers and the demonstration of their clinical utility are similar, and in order to increase the efficiency of SPECTA, SPECTApath ensures the consistency of biomarker development.

**SPECTAreg** – partnership with drug developers is only possible if there is regulatory acceptance of the processes. Such initiatives require new forms of ethical and regulatory clearance so that any emerging biomarker can be efficiently imported. SPECTAreg handles these types of issues so that Europe remains attractive for early drug development.

**SPECTAforum** – a place for involved stakeholders to meet and break breakdown solitary and inefficient approaches.

www.EORTC.org

The first EORTC Cancer Survivorship Summit was held in January 2014. What were your personal highlights of this event?

The success of the summit surpassed our expectations. Here again, new partnerships with new players such as insurers and bankers were really breakthrough developments. The central role played by patient advocacy groups was also a major achievement of the summit. We identified new, unmet needs of cancer survivors, and their disparities across Europe were highlighted. These will now form the basis for new areas of research. Due to the overwhelming success of the summit, we have decided to organise another EORTC Cancer Survivorship Summit in 2016.

Patients also benefit from longitudinal follow up of tumour evolution in case of relapse. A single informed consent patient signature is needed to screen for basic tumour molecular characteristics as well as for current and future molecular biomarkers, which opens the possibility for potential inclusion into clinical studies.

SPECTA also offers agile partnership models for drug developers and pharmaceutical industry. It has economically attractive cost-sharing models thanks to immediate access to pre-screened patients, timely activation of specific downstream studies via pre-agreed regulatory models, development of standardised quality assurance and quality control (QA/QC) procedures in consultation with regulators, and matched opportunities for tumour-drug, drug-biomarker, biomarker technology and drug developer/academic researchers.

Scientists gain new research opportunities such as integrated clinical research infrastructure in international settings, facilitated operations through a single entry point to access multiple studies, high quality annotated material access for research purposes, longitudinal follow up of patients to understand progression patterns, comparable outcomes obtained through similar processes and a global approach that covers complete biomarker study portfolios.

SPECTA also has state-of-the-art validation access for technologies and diagnostics, emerging technologies, QA/QC-based drug development, high quality biological sample access, and multidisciplinary and regulatory expertise access. With research strategies such as SPECTA, the EORTC is defining the future of cancer therapy.

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