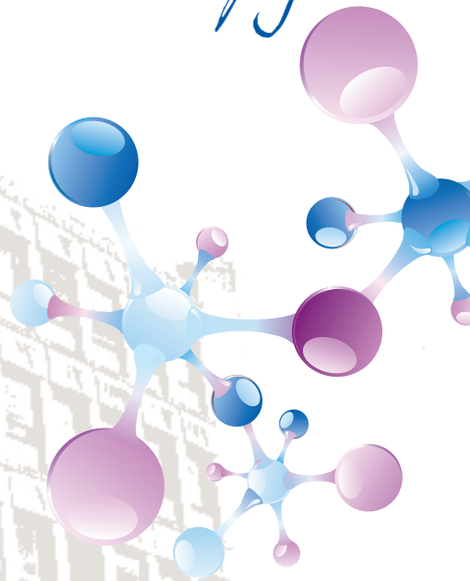
EUROPEAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER

MISSION & STRUCTURE

2012 - 2013

The future of cancer therapy



EORTC 2012 - 2013

EORTC
European Organisation for Research and Treatment of Cancer
50 years of Progress Against Cancer

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The future of cancer therapy

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EORTC
1962 - 2012
50 years of Progress Against Cancer

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D/2012/6136/001
ISBN 978-2-930064-43-7

EUROPEAN ORGANISATION FOR RESEARCH & TREATMENT OF CANCER

2012 - 2013

EORTC

The future of cancer therapy

The EORTC is all about science and progress in cancer care

Over 50 years ago, visionary leaders in cancer medicine realized that advancement of patient management requires solid understanding of the disease and biology, vigorous testing of novel treatments, and interdisciplinary collaboration and exchange beyond state boundaries. This remains true today, and is even more important as we move into an era of personalized medicine.

Platforms for molecular testing are needed to profile each patient's tumor. Novel tools and imaging methods allow for adequate and early evaluation of the treatment effect. The EORTC is well positioned to provide the needed network and infrastructure to advance science and new treatments. The EORTC Headquarters staff is eager to contribute and help, and we sincerely thank them here for their continued commitment.

Oncology has grown from small sub-disciplines of internal medicine, radiation therapy or surgery, respectively, to a large specialty of its own. The tremendous increase in knowledge, understanding, and treatment has led to organ-based specialization as is reflected in the EORTC Groups structure. As we move forward, interdisciplinarity, the integration of pharmacology, molecular biology, tumor immunology, and imaging, as well as transversal problem solving beyond organ-based medicine, are gaining increasing importance.

Challenges ahead

The complexity of biology, the interaction of tumor and its stroma, and a plethora of agents to be tested are challenges and opportunities to rational trial design and conduct. We now understand that there may be common pathways leading to tumor proliferation. Novel treatment strategies are oriented towards the specific molecular aberrations. Molecular tumor characterization is becoming routine also in daily practice. The input of well-trained biologists is needed in order to understand the requirements and limitations of clinical decision making. Clinicians, for their part, need to understand the limitations of molecular techniques, the importance of quality assurance, test reliability, specificity, and sensitivity.

The regulatory environment has changed over the past decade. What was meant to lead to harmonization allowing for rapid translation from the bench to the clinic has resulted in heavy administrative requirements. Patient information sheets resemble the fine print of complex legal language and do not contribute to a true informed consent. What was meant as protection of patients' rights and interests and enhanced patient safety results in confusion for the patients in an already difficult period their lives. Obstruction to novel and promising treatments is the consequence. Constructive lobbying, in particular also by the EORTC, directed towards an explanation of the limitations of the current directive has not gone unheard, and a revised proposal of the clinical trials directive is in circulation.

The economic downturn limits the available financial resources for cancer research and the care of cancer patients. The best response to scarce resources is to collaborate and share competences. The EORTC has a long-standing partnership with industry adhering to strict standards of trial quality and academic independence. This partnership has led to a number of practice-changing trials. The quality of EORTC investigators has been confirmed by repeated inspections by national competent authorities, and EORTC trial results have allowed for registration of several new drugs or indications.

The complexity of clinical trials, as well as the expansion into countries outside the EORTC network, requires new models of collaboration. Examples of new and fruitful collaboration are on its way, a win-win situation for industry and academia; the ultimate winners are our patients.

Novel sources of funding are needed. The EORTC is a partner in seven EU projects. The partnership with Alliance Boots and the EORTC Charitable Trust is recognition of the value that the EORTC brings to cancer research. This partnership has enabled the initiation of a unique biobank and molecular tumor characterization platform in colorectal cancers. Unique is not only the partnership, but also the close linking of a tissue platform with clinical trials and thus homogenous treatment and outcome data. Those of you who have participated in these activities can testify to the dedication and commitment of the leadership and the employees of Alliance Booth. We thank the EORTC Charitable Trust and Alliance Boots for this visionary initiative.

Patient advocacy

Patient and patient advocacy groups are becoming increasingly involved in both individual and politico-scientific decisions of cancer care. We need to learn to listen to patients' representatives, and they will need to understand the difference between an individualized decision and trials designed to provide care for an entire group of patients.

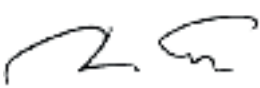
Opening up of groups - transversal and international collaboration

New models of interaction and exchange among academics are needed. Certain treatments and treatment modalities may be applicable across several tumor types. The importance of transversal platforms and continuous interaction and collaboration are of utmost importance. Boundaries, be it disciplines, specialties, or state, must be overcome. International collaboration (also beyond Europe) and outreach is required.

Translational research

A better understanding of the disease and understanding why our interventions fail or succeed is an obligation. Nevertheless, with the excuse of patients' interests and legal considerations, access to biological material is often being hindered; tissue collection and exchange are made particularly difficult. Some institutions do not allow the sharing of material despite a patient's explicit authorization, regulators do not allow tissue to cross state borders, and even we as investigators sometimes prefer to store tumor tissues for future use (?) in our basements. Ethical considerations are often brought forward, while in actuality ethics warrants that we learn a maximum from each patient in order to minimize the number of times we make the same mistakes.

With these thoughts we look forward to a continued and fruitful collaboration and thank you for your trust and friendship.



Roger Stupp
EORTC, President

Françoise Meunier
EORTC, Director General

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Structure and Organisation

EORTC Headquarters (located in Brussels) deals with all scientific, legal, and administrative issues related to the EORTC.

Arrangements have been made for the US NCI Liaison Office to be located adjacent to the EORTC Headquarters. Moreover, the European CanCer Organisation (ECCO), the European Oncology Nursing Society (EONS) la Société Internationale d'Oncologie Pédiatrique Europe (SIOP Europe), and the European Society of Surgical Oncology (ESSO) are also located in the same building as the EORTC.

The aims of the European Organisation for Research and Treatment of Cancer (EORTC) are to develop, conduct, coordinate, and stimulate translational and clinical research in Europe to improve the management of cancer and related problems by increasing survival but also patient quality of life. Extensive and comprehensive research in this wide field is often beyond the means of individual European hospitals and can be best accomplished through the multidisciplinary multinational efforts of basic scientists and clinicians.

The ultimate goal of the EORTC is to improve the standard of cancer treatment through the testing of more effective therapeutic strategies based on drugs, surgery and/or radiotherapy that are already in use. The EORTC also contributes to the development of new drugs and other innovative approaches in partnership with the pharmaceutical industry. This is accomplished mainly by conducting large, multicenter, prospective, randomized, phase III clinical trials. In this way, the EORTC facilitates the passage of experimental discoveries into state of the art treatments.

Through translational and clinical research, the EORTC offers an integrated approach to drug development, drug evaluation programs and medical practices.

EORTC Headquarters, a unique pan European clinical research infrastructure, is based in Brussels, Belgium, from where its various activities are coordinated and run.

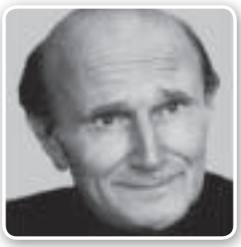
The EORTC is both multinational and multidisciplinary, and the EORTC Network comprises over 300 hospitals and cancer centers in over 30 countries which include some 2,500 collaborators from all disciplines involved in cancer treatment and research.

The 170 members of the EORTC Headquarters staff handle some 6,000 new patients enrolled each year in cancer clinical trials, approximately 30 protocols that are permanently open to patient entry, over 50,000 patients who are in follow-up, and a database of more than 180,000 patients.

Intergroup collaboration is also promoted to face current challenges of clinical trials aiming at targeted therapies in order to recruit a large number of patients within a reasonable period of time.

History

The EORTC was founded as an international organization under Belgian law in 1962 by eminent oncologists working in the main cancer research institutes of the EU countries and Switzerland. It was named the Groupe Européen de Chimiothérapie Anticancéreuse (GECA) and became the EORTC in 1968.



Georges Mathé
Villejuif, France
(1962-1965)

Silvio Garattini
Milan, Italy
(1965-1968)

Dirk Willem van Bekkum
Rijswijk, The Netherlands
(1969-1975)

Henri Tagnon
Brussels, Belgium
(1975-1978)

Lazlo George Latja
Manchester, United Kingdom
(1979-1981)

Carl Gottfried Schmidt
Essen, Germany
(1981-1984)

Umberto Veronesi
Milan, Italy
(1985-1988)

Louis Denis
Antwerp, Belgium
(1988-1991)

Emmanuel van der Schueren
Leuven, Belgium
(1991-1994)

Gordon McVie
London, United Kingdom
(1994-1997)

Jean-Claude Horiot
Dijon, France
(1997-2000)

Allan T. van Oosterom
Leuven, Belgium
(2000-2003)

Alexander M.M. Eggermont
Rotterdam, The Netherlands
(2003-2006)

Martine Piccart
Brussels, Belgium
(2006-2009)

Jean-Yves Blay
Lyon, France
(2009-2012)

Roger Stupp
Lausanne / Zurich, Switzerland
(2012-2015)

FULL MEMBERS (voting)

Roger Stupp
President

Jean-Yves Blay
Past President

Vincent Grégoire
Vice-President

Fatima Cardoso
Secretary General

Emiel Rutgers
Treasurer

Martin van den Bent
Chair of Clinical Research Division

Nadia Harbeck
Chair of Translational Research Division

Ahmad Awada
Chair of Independent Data Monitoring Committee

Sabine Tejpar
Chair of Translational Research Advisory Committee

Christian Dittrich
Chair of New Drug Advisory Committee

Frances Shepherd
Chair of Protocol Review Committee

Ian Tannock
Chair of Scientific Audit Committee

Karin Haustermans
Chair of Quality Assurance Committee

FULL MEMBERS (voting) - *Cont'd*

Piotr Rutkowski
Chair of Membership Committee

Dean Fennell
Member

Eric Van Cutsem
Member

Jan van Meerbeeck
Member

EX-OFFICIO MEMBERS (non-voting)

Sir Christopher Mallaby
Chair, The EORTC Charitable Trust

Victoria Agnew
Executive Secretary, The EORTC Charitable Trust

Françoise Meunier
Director General, EORTC

AM.M. Eggermont
Editor-in-Chief, EJC

Jean-Claude Horiot
EJC Liaison Officer

Susanne Radtke
Director EU Activities, NCI Center for Global Health EU Liaison Office

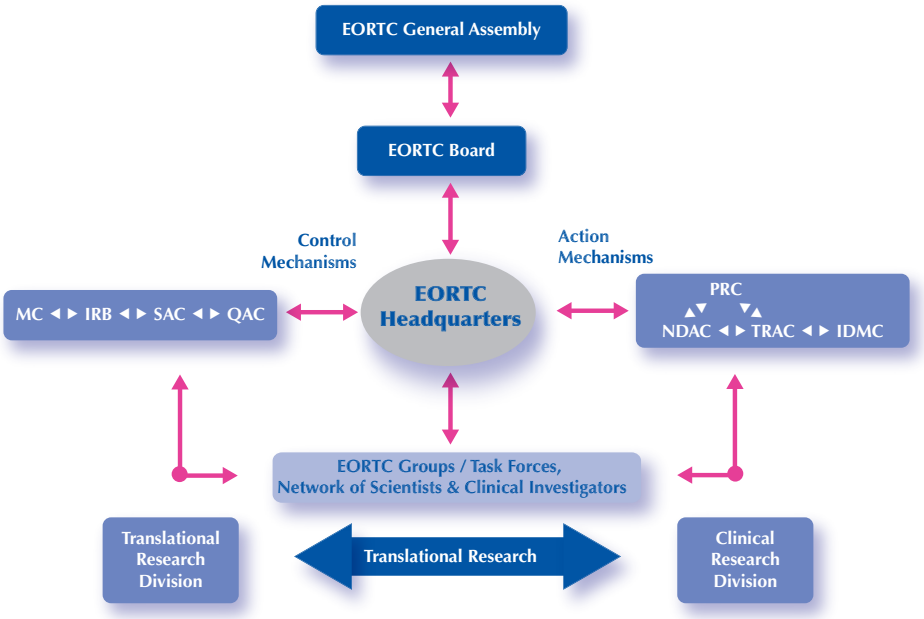
Denis Lacombe
Director, EORTC

The General Assembly is the legislative body of the EORTC. The General Assembly delegates specific functions to the Board, Committees, or appointed persons.

The EORTC Network is organized into groups of scientists and/or clinicians, each with a specific area of interest in cancer research. These groups conduct translational research and/or clinical trials on all types of cancers using a multidisciplinary approach. The effective voting members of the General assembly are the President, the past three Presidents, each Group Chair, the Task Force Chairs, each of the Committee Chairs, and a representative from each of the top 15 accruing institutions. The General Assembly meets at least once a year and elects a new EORTC Board once every three years.

The Board is the steering and executive body which advises the General Assembly on new activities and formulates proposals to be ratified by the General Assembly. The Board meets at least twice a year. The Board consists of elected (voting) members and several *ex officio* members. The Board members select among themselves the President, Vice-President, Treasurer, and Secretary General.

Since 2011, a modification of the statutes allows the appointment of a President-elect. This was done for the first time when R. Stupp was appointed as President-elect in June 2011.



EORTC Committees

MC: Membership Committee, **IRB:** EORTC Headquarters Institutional Review Board, **SAC:** Scientific Audit Committee, **QAC:** Quality Assurance Committee, **PRC:** Protocol Review Committee, **NDAC:** New Drug Advisory Committee, **TRAC:** Translational Research Advisory Committee, **IDMC:** Independent Data Monitoring Committee

The General Assembly of EORTC is composed of effective members (voting and non-voting).

EFFECTIVE VOTING MEMBERS

Acting President	**R. Stupp, Lausanne / Zurich (CH)**
Past Presidents (last three)	J-Y. Blay, Lyon (FR)
	M. Piccart, Brussels (BE)
	A.M.M. Eggermont, Villejuif (FR)

EORTC Groups Chairs

Brain Tumor	W. Wick, Heidelberg (DE)
Breast Cancer	D. Cameron, Edinburgh (UK)
Children's Leukemia	Y. Benoit, Gent (BE)
Gastrointestinal Tract Cancer	A. Roth, Geneva (CH)
Genito-Urinary Cancers	B. Tombal, Brussels (BE)
Gynecological Cancer	A. Casado-Herraez, Madrid (ES)
Head & Neck Cancer	L. Licitra, Milano (IT)
Imaging	N. deSouza, Sutton (UK)
Infectious Diseases	P. Donnelly, Nijmegen (NL)
Leukemia	J-P. Marie, Paris (FR)
Lung Cancer	M. O'Brien, Sutton (UK)
Lymphoma	R. van der Maazen, Nijmegen (NL)
Melanoma	A. Testori, Milano (IT)
PathoBiology	J. Martens, Rotterdam (NL)
Pharmacology & Molecular Mechanisms	G.J. Peters, Amsterdam (NL)
Quality of Life	M. Groenvold, Copenhagen (DK)
Radiation Oncology	P. Maingon, Dijon (FR)
Soft Tissue & Bone Sarcoma	W. van der Graaf, Nijmegen (NL)

EORTC Task Forces Chairs

Cancer in the Elderly	H. Wildiers, Leuven (BE)
Cutaneous Lymphoma	R. Stadler, Minden (DE)
Endocrine Tumors	M. Schlumberger, Villejuif (FR)

EORTC Committees / Divisions Chairs

Clinical Research Division (CRD)	M. van den Bent, Rotterdam (NL)
Translational Research Division (TRD)	N. Harbeck, Munich (DE)
Independent Data Monitoring Committee (IDMC)	A. Awada, Brussels (BE)
Membership Committee (MC)	P. Rutkowski, Warsaw (PL)
New Drug Advisory Committee (NDAC)	C. Dittrich, Vienna (AT)
Protocol Review Committee (PRC)	F. Shepherd, Toronto (CA)
Quality Assurance Committee (QAC)	K. Haustermans, Leuven (BE)
Scientific Audit Committee (SAC)	I. Tannock, Toronto (CA)
Translational Research Advisory Committee (TRAC)	S. Tejpar, Leuven (BE)

Representatives from the 15 top Academic Recruiting Institutions

Institut Curie, Paris & Saint-Cloud (FR)	V. Diéras
Institut Gustave Roussy, Villejuif (FR)	M. Ducreux
The Netherlands Cancer Institute-Antoni Van Leeuwenhoekziekenhuis, Amsterdam (NL)	E. Rutgers
Clinique Saint Elisabeth, Namur (BE)	P. Vuylsteke
Hôpitaux Universitaires Bordet-Erasme, Brussels (BE)	A. Awada
Centre Georges-François-Leclerc, Dijon (FR)	P. Fumoleau
UZ Leuven, Leuven (BE)	I. Vergote
Leiden University Medical Centre, Leiden (NL)	H. Gelderblom
Universitaetsklinikum Heidelberg, Heidelberg (DE)	M. Platten
Christie NHS Foundation Trust, Manchester (UK)	C. Faivre-Finn
Centre Léon Bérard, Lyon (FR)	O. Tredan
Universitaetsspital, Zurich (CH)	M. Weller
Arnhem's Radiotherapeutisch Instituut, Arnhem & Harderwijk (NL)	R. Keus
UZ Rotterdam, Rotterdam (NL)	S. Sleijfer
Medisch Centrum Haaglanden, Den Haag & Leidschendam (NL)	M. Taphoorn

GENERAL ASSEMBLY EFFECTIVE NON-VOTING MEMBERS

Board Members

Vice-President	V. Grégoire, Brussels (BE)
Secretary General	F. Cardoso, Lisbon (PT)
Treasurer	E. Rutgers, Amsterdam (NL)
Members	D. Fennell, Leicester (UK)
	E. Van Cutsem, Leuven (BE)
	J. van Meerbeeck, Gent (BE)

Other Effective Non-Voting Members

Director General, EORTC	F. Meunier, Brussels (BE)
Director, EORTC	D. Lacombe, Brussels (BE)
Chairman, The EORTC Charitable Trust	Sir Christopher Mallaby, London (UK)
Editor-in-Chief, European Journal of Cancer (EJC)	A.M.M. Eggermont, Villejuif (FR)
EJC Liaison Officer	J-C. Horiot, Genolier (CH)
Executive Secretary, The EORTC Charitable Trust	V. Agnew, London (UK)
Director European Activities, NCI Center for Global Health European Liaison Office	S. Radtke, Brussels (BE)

Past Presidents (other than the last 3)

A.T. van Oosterom (BE)

J-C. Horiot (FR)

J.G. McVie (UK)

L. Denis (BE)

U. Veronesi (IT)

D. van Bekkum (NL)

S. Garattini (IT)

Effective Membership

All members of the General Assembly are effective members of the EORTC. In addition, members of the EORTC Groups / Task Forces and EORTC Committees are associate members of the organization.

Associate Membership

Investigators who recruit patients into EORTC clinical trials and contribute to laboratory research conducted for these clinical studies or to other EORTC activities approved by the Board are admitted as associate members. They must be natural persons.

Applications of candidate associate members are submitted for assessment by the Membership Committee. They may be submitted by the candidate directly or by a Group Chair. The Membership Committee delivers its recommendation to the Board. A Group Chair may appeal to the General Assembly against the refusal of an application he or she had submitted.

Associate membership is granted for an initial probationary period ending immediately prior to the date of the third ordinary General Assembly held after the admission of the associate member. Associate membership can then be renewed for successive periods of three years. The Board decides on the renewals at its last meeting before each ordinary General Assembly. A Group Chair may appeal to the General Assembly against the refusal to renew the associate membership of a member of his or her group.

The Board may withdraw the associate membership from members who no longer meet the admissibility criteria applied by the Board (a minimum of 15 patients recruited over the last three years across all EORTC Groups / Task Forces).

In some circumstances, other types of membership may be considered for scientists who bring a substantial contribution to the activities of a group without recruiting patients into clinical trials (basic scientists, pathologists, and radiologists, etc.). Foreign membership may be considered for 'temporary' affiliation of an institution with an EORTC Group in the context of a specific clinical trial provided that EORTC rules allowing foreign membership have been followed.

For any further information regarding membership, please contact the EORTC Membership Committee at the following address: membership@eortc.be

All EORTC scientific activities are conducted within multidisciplinary groups divided into the Translational Research and Clinical Research Divisions. Emphasis is placed on translational research and cooperation between EORTC Groups and Task Forces.

This forms the basis of a network of oncology specialists including clinical experienced investigators and study coordinators as well as experienced translational research and laboratory scientists.

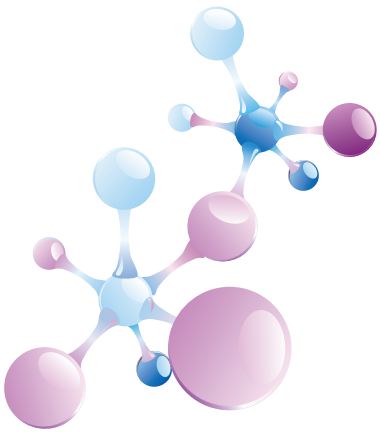
EORTC research offers an integrated approach to the evaluation of innovative agents, a comprehensive clinical trial program, multimodality therapeutic strategic evaluation, and research projects including the study of quality of life and patient reported outcomes.

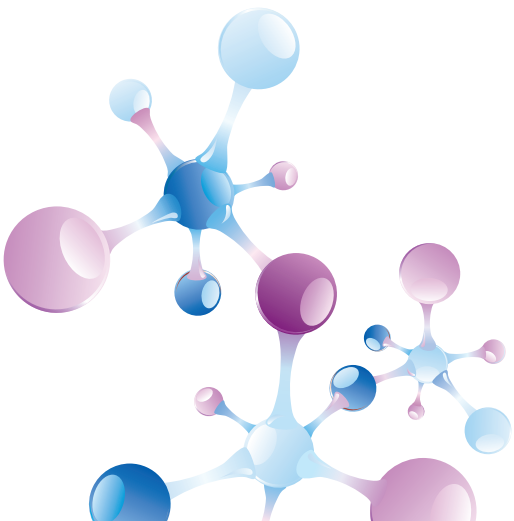
In cooperation with the clinical groups, the EORTC Translational Research Division, which includes the Pharmacology and Molecular Mechanisms, Pathobiology, and Imaging Groups, focuses on pre-clinical testing of new anticancer agents, receptors, and tumor markers. It also provides support for translational research projects conducted within the EORTC on pharmacology and molecular mechanisms, pathology, and imaging.

The EORTC Clinical Research Division is mainly involved in the conduct of clinical trials through either tumor-specific groups (Brain Tumor, Breast Cancer, Melanoma, Leukemia, etc.) or modality-oriented cooperative groups such as the Radiation Oncology Group.

Groups are created and dissolved by decision of the EORTC Board. The EORTC Board may set up task forces which may possibly be converted into groups after a probationary period and SAC review.

Individuals interested in forming a Group should contact EORTC Headquarters to obtain guidance as to where they would best fit into the EORTC structure.





The EORTC is funded through several sources including the EORTC Charitable Trust providing a core grant which is mainly supported by numerous national cancer leagues.

Since 1972, the US National Cancer Institute (NCI) has provided core support to EORTC Headquarters, and with this support a close scientific collaboration has been maintained to promote transatlantic research projects.

A core grant from the Fonds Cancer, FOCA (BE), provides support for the EORTC Headquarters staff.

EORTC Headquarters receives annual grants allocated by BELSPO (the Belgian Federal Science Policy Office) and by the Belgian National Lottery.

Funding for the Fellowship Program is obtained from several sources including the Vlaamse Liga tegen Kanker, the Dutch Konigin Wilhehmina Fonds Kankerbestrijding, the Schroeder Foundation, the Melvin Seiden Foundation, and the Pfizer Foundation (within the framework of the PROBE Project). This funding program is coordinated by the EORTC Charitable Trust.

In addition to support from the EORTC, fellowships for medical doctors are also provided on ongoing basis by the Fonds Cancer / FOCA (Belgium), since 1991.

On the occasion of the 50th Anniversary of the EORTC (March 2012), a fellowship has been allocated by Bristol Myers Squibb (BMS) to evaluate new models of partnership between academia and industry.

In addition, grants for EORTC research projects are received from the European Commission under the 6th and the 7th Framework Programme and the Innovative Medicines Initiative (IMI).

Clinical studies evaluating new drugs for potential registration or testing innovative therapeutic agents, including some educational projects, are conducted in cooperation with pharmaceutical industry partners.

Pharmaceutical industry sponsorship is also provided in the form of 'unrestricted grants' for EORTC conferences.

The finances of the EORTC include all accounts from the EORTC Headquarters as well as all EORTC Groups and Task Forces. These accounts are consolidated as required under Belgian Law. The EORTC accounts are audited by Ernst & Young.

The academic research fund

The EORTC Board initiated an Academic Research Fund to support academic clinical trials or research projects submitted to the Board. Selected trials are academic in nature with inadequate or no funding from other sources. A final decision at the Board level is required based on the strategic/ added value the proposed clinical trial brings to the overall EORTC strategy.

Honorary President	**H.R.H. Princess Astrid of Belgium**
Honorary Vice-President	**Sir Ronald Grierson**
Chair	**Sir Christopher Mallaby GCMG, GCVO**

Members of the General Assembly

Chair	**Sir Christopher Mallaby (UK)**
Vice-chair	**Sir David Tang KBE (HK)**
Executive secretary	**Mrs. Victoria Agnew (UK)**
• Professor Jean-Yves Blay	Lyon (FR)
• Mr. Christian Boel	Hellerup (DK)
• Monsieur Alain Camu	Brussels (BE)
• Dr. Gérard Depadt	Lille (FR)
• Professor Alexander M.M. Eggermont	Villejuif (FR)
• H.E. Ambassador Evelyne Genta	Monaco (MC)
• Dr. Jean de Gunzburg	London (UK)
• Mr. Luc van Haute	Brussels (BE)
• Mrs. Elizabeth Hjorth	Copenhagen (DK)
• Mrs. Cora Honing	Amsterdam (NL)
• Professor Jean-Claude Horiot	Genolier (CH)
• Comte Aymar de Lastours	Paris (FR)
• Ms. Kate Law	London (UK)
• Mr. Marc Leland	London (UK)
• Mr. Oscar M. Lewisohn	London (UK)
• Mrs. Sally Lo MBE	Hong Kong (HK)
• H.R.H. Prince Guillaume of Luxembourg	Contern (LU)
• Baroness Suzanne von Maltzahn	London (UK)
• Dr. Rolf Marti	Bern (CH)
• Professor J. Gordon McVie	Milan (IT)
• Professor Françoise Meunier	Brussels (BE)
• Comte Diego du Monceau de Bergendal	Brussels (BE)
• Mr. Hans Neefs	Brussels (BE)
• Dr. Carlos Oliveira	Coimbra (PT)
• Professor Allan T. van Oosterom	Antwerp (BE)
• Mr. Ole Alexander Opdalshei	Oslo (NO)
• Professor Martine Piccart	Brussels (BE)
• H.E. Ambassador Marie-Thérèse Pictet-Althann	Geneva (CH)
• Mrs. Harriet Roth	London (UK/D)
• Dr. Piero Serra	Milan (IT)
• Professor John Smyth	Edinburgh (UK)
• Lady Solti	London (UK)
• Professor Roger Stupp	Lausanne / Zurich (CH)
• Professor Bengt Westermark	Stockholm (SW)

Sir Christopher Mallaby
Chairman of the EORTC Charitable Trust
180 Piccadilly - London W1J 9HF - United Kingdom
Tel.: +44 20 79179571 - Fax : +44 20 74390262
Email: eortccharitrust@btinternet.com

Executive Secretary: Mrs Victoria Agnew

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Avenue de l'Eglise, 10 B
1150 Brussels, Belgium

The EORTC Charitable Trust

In 1976, the EORTC Foundation was established by Royal Decree under the laws of the Kingdom of Belgium as an international association under Belgian Law with the specific aim of raising funds for the activities of the EORTC, to support the structure of the organization, and to support independent academic research projects. It receives substantial funds from National Cancer Charities. All the major European National Cancer Charities which support the work of the EORTC are represented in the General Assembly, as well as the Hong Kong Cancer Fund.

In 2006, the EORTC Foundation changed its name to The EORTC Charitable Trust, to take account of changes in Belgian Law. The aims of The EORTC Charitable Trust remain exactly the same.

Since the last Annual Report, the Charitable Trust has welcomed three new Members to its Council and General Assembly – Professor Roger Stupp, Comte Diego du Monceau de Bergendal, and Mrs. Harriet Roth.

Since the EORTC operates through existing national institutions and hospitals, its financial needs, while growing, are still modest in relation to what it is able to achieve. The financial and economic crisis that began in 2007 and its repercussions have inevitably had an impact on charitable giving and philanthropy. In these difficult circumstances it remains the role and the duty of The Charitable Trust to raise funds for cancer research, and the task is doubly hard. This underlines the vital importance of the continued support of all the National Cancer Charities, and The Charitable Trust would like to express its thanks and appreciation for this.

In 2011 The EORTC Charitable Trust entered into an important partnership with Alliance Boots, the international pharmacy and beauty products group, to create EORTC's Biobank for Colorectal Cancer. This major project will be the first pan-European facility able to create tailored therapies for cancer sufferers through the knowledge now becoming available from the mapping of the human genome. The Biobank will store and analyze tumor samples which will allow scientists to build up a long term picture of the development of the cancers and the individual genes that are associated with them. These advances will enable oncologists to determine which therapy is going to be of most benefit to an individual patient and thus to create a personalized plan of treatment. Alliance

Boots has committed to providing €5,000,000 over five years for this project by fundraising through its companies in Europe and elsewhere. The EORTC Charitable Trust and the EORTC are immensely grateful for this inspired and most generous support. The first EORTC Biobank will be based in Dresden. It is hoped that further EORTC pan European Biobanks in major cancers will be created in the future.

During 2011, The EORTC Charitable Trust received core support of 1,220,914 Euros for the EORTC from various European National Cancer Charities and the Hong Kong Cancer Fund. The Charitable Trust made a core grant of 1,300,000 Euros to the EORTC for the year. During 2011, the Charitable Trust provided funding for fellowships of 43,000 Euros, one of which continued to benefit from the generosity of the Schroder Family Foundation. Also during 2011 the Charitable Trust provided the costs for EORTC's share of the Joint EORTC/CR-UK/NCRI Liaison Office based in Leeds, now in its third year. Additionally, The EORTC Charitable Trust has committed to fund the costs of the EORTC Biobank coordinator, specifically employed to undertake the liaison activities for The EORTC Charitable Trust /Alliance Boots Partnership described above.

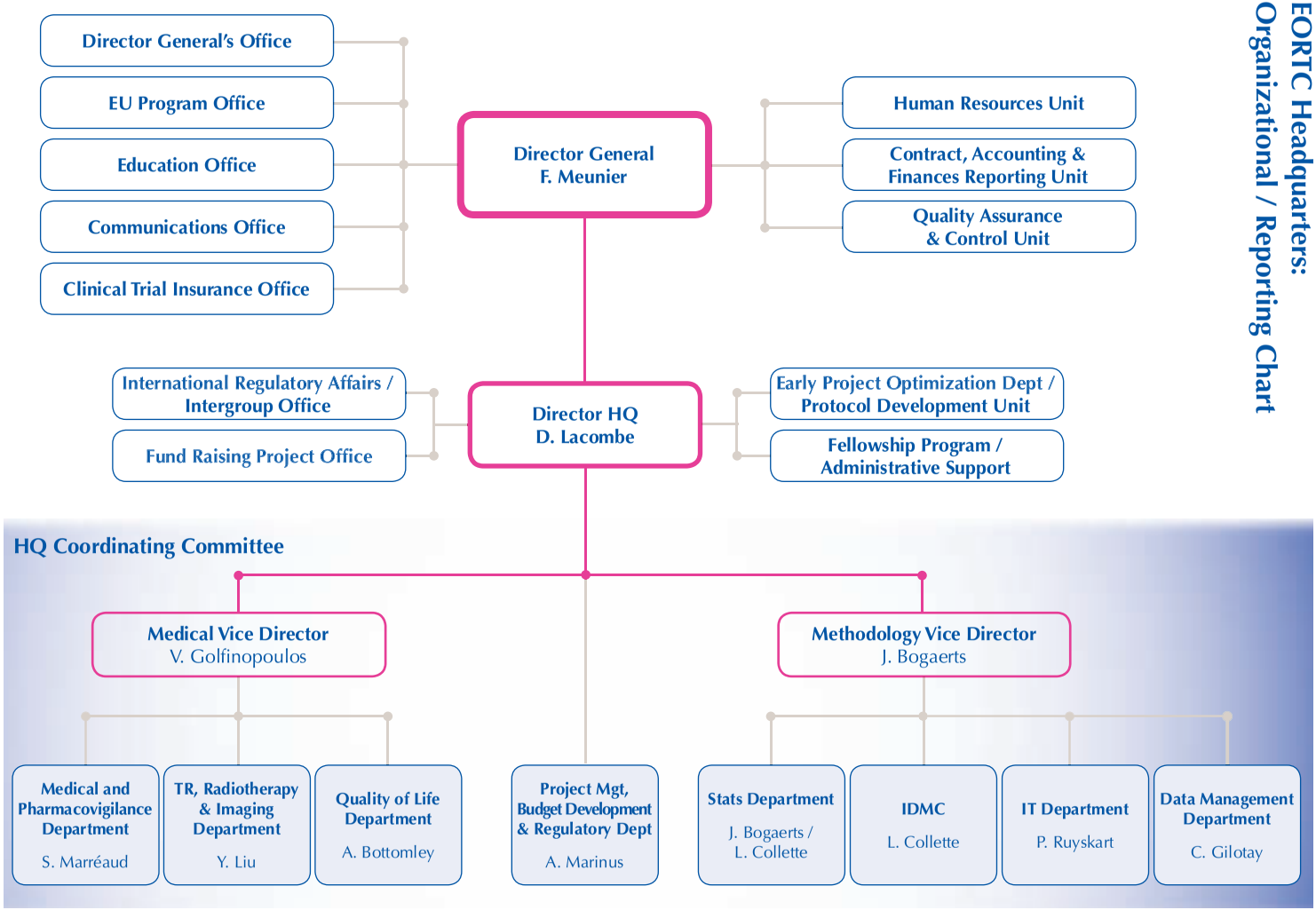
The Charitable Trust organized an innovative fundraising tour in Dresden in May 2011. We believe that fundraising for cancer research has not previously been undertaken by means of tourism. The tour went very well, thanks to the support of Professor Dr Martin Roth, then the Director of the State Museums of Dresden. Our tour over five days enjoyed private viewings of the renowned collections. It culminated in a Gala Dinner in the Residenzschloss in the presence of Their Royal Highnesses Princess Astrid and Prince Lorenz of Belgium. The visit, dinner, and several generous donations produced nearly 200,000 Euros for the Charitable Trust. The Gala evening was sponsored by Vodafone and several private supporters. This was a new venture for the Charitable Trust, and we are considering where we might arrange further tours with the purpose of raising substantial funds for EORTC. It is clear that a combination of great art and architecture with support for the EORTC can succeed in giving pleasure to the participants and benefitting the great cause of cancer research.

In recognition of the 90th Birthday of Sir Ronald Grierson, the Chairman of the EORTC Foundation since its creation in 1976, we decided to celebrate his extraordinary contribution to the cause of cancer research and to the work of the EORTC by raising funds to create a special Fellowship at the EORTC in Clinical Cancer Research. Thanks to the generosity of his many friends, donations have been received to enable the creation of a two year Fellowship in his honor. It will be called the Sir Ronald Grierson Fellowship in Clinical Cancer Research and will be based in Brussels.

In March 2012 we were proud participants in the 50th Anniversary celebrations of the EORTC, a great milestone for this unique organsation. Victoria Agnew and Sir Christopher Mallaby, who are, respectively, in their fourteenth and twelfth years working at The EORTC Charitable Trust, find that their admiration for EORTC and their enjoyment of the work continue to grow with each year.

EORTC Headquarters Staff

EORTC Headquarters: Organizational / Reporting Chart



Director General	**Françoise Meunier, MD, PhD, FRCP**
Director General's Office	
Coordinator	Lily Geyoro, MA
Personal Assistant	Saïda Jinah, BA
Assistant	Alvine Sike, BA
EU Programme	
Officer	Stéphane Lejeune, MPH
Education Office	
Coordinator	Danielle Zimmermann
Communications Office	
Medical Science Writer	John Bean, MA, PhD
Manager	Stéphanie Vandergooten
Assistant	Jennifer Crespo, B Econ
Clinical Trial Insurance Office	
Coordinator	Vicky Minas
Officer	Michèle Lidarssi
Human Resources Unit	
Head of Unit	Bernard Kamp, B Econ
Assistants	Delphine Cnockaert, B Econ
	Nelly Gonay, M Econ
Maintenance Officer	Frédéric Hubinon
Maintenance Staff	Farha Derbal
	Donatella Locci
Secretaries / Receptionists	Sophie Hons
	Alexia Yannopoulos
Contract, Accounting and Finances Reporting Office	
Accounting - Finances Reporting Manager	Ariane Jablonka, M Econ
Accountants	Christophe Bellem, B Econ
	Geneviève Foucart
	Nadia Luboya, B Econ
Accounting Assistant	Aurélia Siraut
Contract Manager	Frédéric Hénot, PhD
Contract Officer	Vicky Konstantakopoulou

Quality Assurance & Control Unit

Head of Unit	Christine de Balincourt, Pharm
Quality and Process Manager	Marie-Laure Couvreur, BSc
Quality Assurance Senior Auditor	Michel Lapaige, MSc, VET
Junior Quality Assurance Auditor	Sarah Morren, VET
Quality Control Coordinator	Christine Waterkeyn, MSc
Clinical Research Associate	Julien Defoiche, PhD
Junior Clinical Research Associate	Gloria Montanes, MSc

Director, EORTC Headquarters — Denis Lacombe, MD, MSc

Executive Secretary	Vicky Minas

Assistant Directors — Andrew Bottomley, PhD; Ann Marinus, RN; Pascal Ruyskart, MSc

International Regulatory Affairs / Intergroup

Head of Office	Anastassia Negrouk, MSc, DEA
Officer	Izabella Jagiello, MSc, PhD

Fund Raising Project Office

Coordinator	Patrick Miqueu, MSc, PhD

Early Project Optimization Department (EPOD) / Protocol Development Unit (PDU)

Head of EPOD Department	**Denis Lacombe, MD, MSc**
EPOD Strategic Development Officers	Anne-Sophie Govaerts, PhD
	Jillian Harrison, PhD
Secretary of EPOD Department	Sonia Pazos, M Econ
Head of PDU Unit	Jillian Harrison, PhD
Protocol Help Desk Officer	Françoise Peeters
Protocol review Committee Secretariat Officer	Gabriel Solbu, MSc

Fellowship Program Unit / Admin. Support

Scientific Coordinator	Denis Lacombe, MD, MSc
Executive Secretary	Vicky Minas
Fellows	Susen Burock, MD
	Divine Ediebah, MSc
	Fei Fei, MD
	Jessica Menis
	Mariano Suppa, MD
	Erik Tanis, MD
	Konstantinos Tryfonidis, MD

Headquarters Coordinating Committee

Jan Bogaerts, ScD
Andrew Bottomley, PhD
Laurence Collette, MSc, PhD
Caroline Gilotay, MSc
Vassilis Golfinopoulos, MD, PhD
Denis Lacombe, MD, MSc
Ann Marinus, RN
Sandrine Marréaud, MSc, MD
Françoise Meunier, MD, PhD, FRCP
Pascal Ruyskart, MSc

Project Management, Budget Development Department and Regulatory Affairs Unit

Head of Department	**Ann Marinus, RN**
Membership Coordinator	Teodora Kirova, BSc
Assistant & Development Manager	Cristel Grimonpont
Senior Clinical Operation Managers	Anouk Allgeier, PhD
	Gaetan de Schaetzen, PhD
Clinical Operation Manager	Kristel Engelen, P.T
Senior Budget Development Manager	Hilde Breyssens, PhD
Senior Projects Manager	Anne Kirkpatrick, MSc
Project Managers	Mélanie Beauvois, MSc, PhD
	Angélique Deleersnijder, PhD
	Nicolas Dif, PhD
	Leslie Herman, PhD
	Julie Hermans, MSc, PhD
	Bénédicte Marchal, MSc, DEA
	Michel Praet, PhD
	Alice Preumont, PhD
	Jonathan Steuve, PhD
	Emilie Varin, PhD
Senior Clinical Trials Assistant	Vinciane Vinckx
Clinical Trials Assistants	Gladdys Arias
	Katrien Baus
	Zineb Bourkiza
	Rachel Ho

Regulatory Unit

Associate Head of Unit	Dominika Misztela, PhD
Managers	Amira Abdelalim, BSc, Pharm
	Jean-Louis Lufimpadio, MSc
	Laura Maher, MSc
Assistants	Alin Arsène, BA
	Julie Coupain, B Econ
	Gandhy Mabiala
	Maria Merodoulaki

Medical Vice Director	Vassilis Golfinopoulos, MD, PhD
Assistant of Medical Department	Michèle Lidarssi

Medical and Pharmacovigilance Department

Head of Medical Department	**Sandrine Marréaud, MSc, MD**
Clinical Research Physicians	Ravi Karra, MD
	Denis Lacombe, MD, MSc
	Sandrine Marréaud, MSc, MD
	Carlo Messina, MD, PhD
	Athanasios Pallis, MD, PhD
	Safaa Ramadan, MD, PhD
	Emad Shash, MD, MSc
Head of Pharmacovigilance Unit	Nathalie Dubois, MSc
Associate Head of Pharmacovigilance Unit	Marie-Pierre Gauthier, PhD
Pharmacovigilance Managers	Nathalie Crokart, MSc, PhD
	Sara Meloen, MSc
	Thomas Valkaert, MSc
Pharmacovigilance Physician	Ravi Karra, MD
Pharmacovigilance Secretary	Sonia Pazos, M Econ

Translational Research, Radiotherapy and Imaging Department

Head of Department	**Yan Liu, MD, PhD**
Associate Head of Department	Jacqueline Hall, PhD
Tumor Bank Administrator	Nawal Bekka, MSc
Secretary	Sonia Pazos, M Econ
Imaging Officer	*To be appointed*
Quality Assurance in Radiotherapy (QART) Unit	
Officer	Vanda Teglas, BSc
Manager	Christos Melidis, MSc

Quality of Life Department

Head of Department	**Andrew Bottomley, PhD**
Translation Team Leader	Dagmara Kulis, MA
Officers	Julie Walker
	Cheryl Whittaker
Specialist in Quality of Life	Francesca Martinelli, MSc
Researcher	Efstathios Zikos, MSc
Research Administrator	Irina Ghislain
Assistants	Rossella Guzzo
	Sheila Scott-Sanderson

Methodology Vice Director	Jan Bogaerts, ScD

Statistics Department

Head of Department	**Jan Bogaerts, ScD**
Senior Statistical Scientist	Richard Sylvester, ScD
Associate Head of Department	Laurence Collette, MSc, PhD
Senior Biostatisticians	Catherine Fortpied, MSc
	Stefan Suciu, PhD
Biostatisticians	Corneel Coens, MSc
	Sandra Collette, MSc
	Thierry Gorlia, MSc
	Baktiar Hasan, PhD
	Saskia Litiere, PhD
	Murielle Mauer, PhD
Junior Biostatistician	Leen Slaets, PhD
Statistical Programmer	Jérôme Rapion, MSc, DESS
Secretary	Zeina Tayah

Independent Data Monitoring Committee

Head of Department	**Laurence Collette, MSc, PhD**
Officer	Gabriel Solbu, MSc

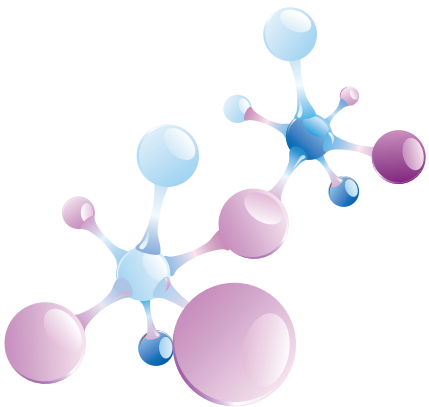
IT Department

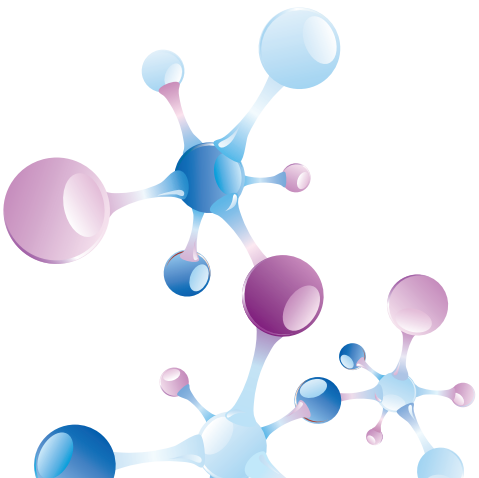
Head of Department	**Pascal Ruyskart, MSc**
Associate Head of Department	Eric Decossaux, MSc
Analyst Programmers	Yves Dohogne, MSc
	Michael Hienny, BSc
	Michel Kirschen, BSc
	Edouard Klopfert, BSc
Computer Application Specialist	Jonathan O'Sullivan
User Support Analyst	Jouri Van den Bergh
System Analyst	Gilles De Vrye, MSc
Senior System Manager	Guillaume Migaszewski

Data Management Department

Head of Department	**Caroline Gilotay, MSc**
Associate Head of Department	Bart Meulemans, MSc
Lead Data Managers	Edith Bastiaens, MSc
	Valérie Dewaste, PhD
	Liv Meert, MSc
	Larissa Polders, MSc
Senior Data Managers	Linda De Prijck, BSc
	Nicole Duez, MSc, RN
	Livia Giurgea, PhD
	Catherine Hermans
	Marie-Ange Lentz, MSc

Data Managers	Fahed Ahssini, MSc
	Isabelle Blangenois, PhD
	Peter De Burghgraeve, MSc
	Linde De Donder, MSc
	Maarten De Rouck, MSc
	Roel Goossens, MSc
	Nils Helsen, MSc
	Sven Janssen, MSc
	Niels Lema, Pharm
	Lies Meirlaen, MSc
	Isabelle Meulders, BSc
	Edwin Nys, MSc
	Axelle Nzokirantevye, MSc
	Christine Olungu, Ir
	Nicolas Othmezouri, MSc
	Tiana Raveloarivahy, BSc
	Françoise Rigaux, BSc
	Seraphine Rossi, MSc
	Virginie Soete, MSc
	Simon Vanderschaeghe, MSc
Development Manager	Steven Deleu, MSc
Training Manager	Marlies Dictus, MSc
Administrative Assistant	Sabrina Decot
Data Entry Clerks	Ilka Debruyne
	Joselma Venas





Several EORTC Committees oversee the strategy and the independence of the EORTC as well as the relevance and scientific value of all research efforts and thereby ensure the highest possible quality of scientific work. Each EORTC Committee Chair is elected to serve a three year term with possibility of renewal upon recommendation by the EORTC Board.

Committees

- EORTC New Drug Advisory Committee (NDAC)
- EORTC Translational Research Advisory Committee (TRAC)
- EORTC Protocol Review Committee (PRC)
- EORTC Scientific Audit Committee (SAC)
- EORTC Quality Assurance Committee (QAC)
- EORTC Independent Data Monitoring Committee (IDMC)
- EORTC Membership Committee (MC)
- EORTC Headquarters Institutional Review Board (IRB)

The aim of the EORTC New Drug Advisory Committee (NDAC) is to expedite the introduction of new drugs into clinical trials within the EORTC. It works closely with EPOD, the Early Project Optimization Department within EORTC Headquarters. In order to ensure a consistent approach towards the pharmaceutical industry, NDAC acts a reference body for all EORTC Groups and makes recommendations to them in all aspects of drug development, including the selection of the most promising compounds. This includes the strategic approach and setting priorities regarding drug development within the entire EORTC Network as well as being a recipient of information from disease oriented groups at the earliest stages of their discussions about trials involving new agents.

The remit of the NDAC are those agents that have not been registered and/or not yet with a role in oncology, or possibly agents which come to the EORTC for the first time in a specific setting. Working very closely with EPOD, NDAC's continued mission is to stimulate, organize and prioritize access to new drugs. It has responsibility for benchmarking the choice of target/ agent and/or company, taking advice from both the disease oriented groups and EPOD. The expectation is that the earlier the involvement of NDAC in the development of a project, the higher the probability that such projects will be approved by the Executive Committee since they will already have been aligned with EORTC priorities.

The NDAC coordinates Advisory Boards/partnership meetings performed with the pharmaceutical industry. The NDAC also supports EPOD regarding methodological issues inherent to innovative agents with new mechanisms of action in the approach of early studies design.

NDAC comments on projects being reviewed by the EORTC Board, and this past year there were 22 such projects, indicating a healthy activity in the generation of new projects within the EORTC.

NDAC is also coordinating a research project aimed at defining new mechanisms based on chronic toxicity criteria for phase I trial of non-cytotoxic agents.

Chair

C. Dittrich, Vienna (AT)

Members

A. Astier, Paris (FR)
A. Awada, Brussels (BE)
U. Banerji, Sutton (UK)
J. Dancey, Kingston (CA)
K. Dhingra, Sparta (US)
J. Martens, Rotterdam (NL)
G. Peters, Amsterdam (NL)
J. Tabernero, Barcelona (ES)

Ex Officio members

N. Harbeck, Munich (DE)
S. Tejpar, Leuven (BE)

The Translational Research Advisory Committee (TRAC) was created to support and provide expert advice from a scientific and practical perspective on translational research (TR) projects conducted within the EORTC. The aims of TRAC are to ensure the independence of the EORTC, the relevance of TR efforts, and to guarantee scientifically sound results so as to increase the scientific visibility of the EORTC. As a pre-clinical scientific advisory committee, TRAC also acts as a permanent EORTC forum between the Clinical and Translational Research Divisions by fostering interest in TR within Clinical Research Division Groups and promoting clinical development ideas/concepts emerging from Translational Research Division Groups.

Missions of TRAC are to:

- Lead Strategic translational research developments within the EORTC;
- Assist EORTC Clinical Groups in optimizing TR studies and integrating TR approaches into their scientific strategy;
- Stimulate EORTC TR projects either as side studies of new EORTC clinical trials or use of existing clinically annotated biosamples;
- Provide expert advice on any TR projects conducted within the EORTC both from scientific and practical perspectives;
- Ensure flow of information between EORTC Translational Research and Clinical Research Divisions and contribute to reinforcement of the EORTC platform of pathologists and scientists;
- Support the EORTC Headquarters TR team and EPOD (Early Project Optimization Department).

TRAC comprises permanent and ex officio members. All of the main disciplines of TR in oncology are represented in the review panel. Each member is elected for a renewable three-year term.

Chair

S. Tejpar, Leuven (BE)

Vice-chair

MG. Daidone, Milan (IT)

Members

M. Bendszus, Heidelberg (DE)
F. Cardoso, Lisbon (PT)
N. de Souza, Sutton (UK)
M. Debiec-Rychter, Leuven (BE)
T. De Witte, Nijmegen (NL)
D. Fennell, Leicester (UK)
C. Fink, Mannheim (DE)
O. Hoekstra, Amsterdam (NL)
M. Hegi, Lausanne (CH)
R. Iggo, Bordeaux (FR)
P. Lambin, Maastricht (NL)
J. Martens, Rotterdam (NL)
S. Michiels, Brussels (BE)
G. Peters, Amsterdam (NL)
I. Skvortsova, Innsbruck (AT)
F. Sweep, Nijmegen (NL)
R. Salgado, Brussels (BE)
P. Verhagen, Rotterdam (NL)
N. Zaffaroni, Milan (IT)

Ex Officio members

J. Hall, Brussels (BE)
N. Harbeck, Munich (DE)
C. Dittrich, Vienna (AT)

Chair F. A. Shepherd, Toronto (CA)
Vice-chair M. Eriksson, Lund (SE)

Members

J-P. Armand, Paris (FR)
F. Baron, Liège (BE)
J. Bernier, Genolier (CH)
L. Blomqvist, Stockholm (SE)
S. Bodis, Aarau (CH)
F. Brunotte, Dijon (FR)
A. Chiti, Rozzano (IT)
K. Conlon, Dublin (IE)
A. Craft, Newcastle (UK)
T. de Witte, Nijmegen (NL)
V. Diéras, Paris (FR)
C. Dittrich, Vienna (AT)
P. Goodwin, Toronto (CA)
F. Guillemin, Vandoeuvre-Les-Nancy (FR)
C. Hill, Paris (FR)
N. Isembert, Dijon (FR)
A. Jimeno, Aurora (US)
O. S. Nielsen, Aarhus (DK)
J. Oliveira, Lisbon (PT)
M. Parmar, London (UK)
R. Rosell, Badalona (ES)
A. Sobrero, Genoa (IT)
B. van Beers, Clichy (FR)
G. Velikova, Leeds (UK)
C. Weltens, Leuven (BE)

Phase I-II prc experts

J. Cassidy, Glasgow (UK)
M. De Jonge, Rotterdam (NL)
H. Dumez, Leuven (BE)
A. Elias, Aurora (US)
H.W. Hirte, Hamilton (CA)
I.R. Judson, London (UK)
P.J. O'Dwyer, Philadelphia (US)
W. Parulekar, Kingston (CA)
A. Ravaud, Bordeaux (FR)
D. Ross Camidge, Denver (US)
L. Seymour, Kingston (CA)
L. Siu, Toronto (CA)

Ex Officio

D. Lacombe, Brussels (BE)
F. Meunier, Brussels (BE)

All protocols conducted by the EORTC need to be approved by an independent panel of experts. The Protocol Review Committee (PRC) appointed by the EORTC Board reviews all projects proposed by EORTC Groups. The EORTC has introduced an expedited process of mutual recognition of external independent review for Intergroup projects lead by non-EORTC groups which have the prior approval of an equivalent review process, e.g. by US National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) or Cancer Research UK (CRUK) Clinical Trials Awards and Advisory Committee (CTAAC).

For a study to be conducted under the EORTC label, EORTC experts must have an impact on the study design and the project has to be approved by the PRC. In addition, the database should be handled by EORTC Headquarters (HQ) staff and the final analysis should be performed by an EORTC statistician unless conducted by another independent research group in the context of a so-called intergroup clinical trial.

The PRC comprises experts in the field of cancer clinical research. All disciplines of oncology are represented in the review panel. About 50% of the PRC members are non-EORTC members, and selected projects are reviewed by a representative of the NCI CTEP. Additionally, the PRC makes

systematic use of external reviewers - a minimum of three international experts are consulted for each outline thereby providing independent review.

The Protocol Development Unit (PDU) follows the overall protocol development and approval process. Full protocols must be a faithful development of approved outlines. Significant modifications of the study outline after its approval will need to be approved again by the PRC. If the modifications have an impact on the resources to be allocated by the EORTC, the decision of the EORTC Board to have the study supported by the EORTC may be reconsidered. After a protocol is approved and released any change is deemed an amendment. The PRC approves scientific amendments to EORTC protocols and the PDU coordinates their implementation into protocols.

All efforts are made to speed up the review process in order to activate protocols quickly, but the PRC must make sure that all studies with the EORTC label are conducted according to the highest possible standards (scientific, administrative and regulatory) of clinical scientific investigation. The New Drug Advisory Committee (NDAC), the Translational Research Advisory Committee (TRAC) including imaging and the Cancer in the Elderly Task Force provide additional scientific expertise when needed.

Summary of the Protocol Review Committee activities from 01 January 2011 until 30 June 2012

Between 01 January 2011 and 30 June 2012 (refer to table), 25 outlines were submitted. Reviews and decisions were made by the PRC for a total of 24 outlines (eight Phase II, one Phase II/III, twelve Phase III studies and three research projects). Of these, 19 were accepted, four remain pending for resubmission and one was rejected. Currently two outlines are in review process and two were cancelled during review due to changes in company development strategy.

Outlines reviewed from 01 January 2011 until 30 June 2012 (sorted by date of first outline submission)

Study number	Groups	Phase	EORTC strategic classification	1st outline submission date	Latest decision date for the outline	Latest decision for the outline
40085-75083	Gastrointestinal Tract Cancer + Elderly Taskforce	II	2	12/08/2010	26/01/2011	Accepted
17101-23102	Endocrine Task + Imaging	III	1A	14/10/2010	02/03/2011	Accepted
06101-75101(1)	Leukemia + Elderly Taskforce	III	3A	19/10/2010	19/12/2011	Accepted
90103	Network Of Core Institutions	II	2	03/01/2011	28/02/2011	Cancelled during review

Study number	Groups	Phase	EORTC strategic classification	1st outline submission date	Latest decision date for the outline	Latest decision for the outline
10096-22093(1)	Breast Cancer + Radiation Oncology	III	1A	21/01/2011	09/03/2011	Rejected
55102(2)	Gynecological Cancer	III	1C	27/01/2011	09/03/2011	Accepted
20101-23101	Lymphoma + Imaging	III	1A	03/02/2011	16/08/2011	Accepted
90111-24111	Network Of Core Institutions + Head and Neck Cancer	II	Other	28/02/2011	31/05/2011	Accepted
10112(2)	Breast Cancer	III	1C	06/04/2011	17/05/2011	Accepted
40CRC	Gastrointestinal Tract Cancer	Screening platform	Other	16/06/2011	17/10/2011	Accepted
10113(2)	Breast Cancer	III	1A	20/06/2011	04/04/2012	Cancelled during review
55111(2)	Gynecological Cancer	III	1C	22/06/2011	16/08/2011	Accepted
62112	Soft Tissue and Bone Sarcoma	II	3C	04/07/2011	24/11/2011	Accepted
22111-26111	Radiation Oncology + Brain Tumor	III	1A	12/07/2011	28/09/2011	Resubmit
20111(1)	Lymphoma	Survey and TR	Other	18/07/2011	22/11/2011	Accepted
30111-22112(1)	Genito-Urinary Cancers + Radiation Oncology	III	1A	02/08/2011	09/11/2011	Accepted
26112-22115	Brain Tumor + Radiation Oncology	II	2	04/08/2011	13/10/2011	Accepted
22114-40111(2)	Radiation Oncology + Gastrointestinal Tract Cancer	II/III	1C	10/08/2011	25/10/2011	Accepted
08114	Lung Cancer	Registry and TR	Other	19/08/2011	23/11/2011	Accepted
75111-10114	Elderly Taskforce + Breast Cancer	II	3C	22/09/2011	23/11/2011	Accepted

Study number	Groups	Phase	EORTC strategic classification	1st outline submission date	Latest decision date for the outline	Latest decision for the outline
22113-08113	Radiation Oncology +	II	2	30/09/2011	22/11/2011	Accepted
55116-62114(2)	Gynecological Cancer + Soft Tissue and Bone Sarcoma	III	1C	16/12/2011	03/01/2012	Accepted
55112-62111(1)	Gynecological Cancer + Soft Tissue and Bone Sarcoma	II	2	16/12/2011	15/02/2012	Resubmit
62113-55115(1)	Soft Tissue and Bone Sarcoma + Gynecological Cancer	II	Other	16/12/2011	14/03/2012	Accepted
1209-EnTF	Endocrine Task	II	3B	02/05/2012	21/06/2012	Resubmit
1205-LCG	Lung Cancer	II	3C	03/05/2012	(04/07/2012)	In review process (Resubmit)
1211-GUCG-IG	Genito-Urinary Cancers + Imaging	II	3B	04/05/2012	14/06/2012	Resubmit
1207-GITCG-IG	Gastrointestinal Tract Cancer + Imaging	II/III	3B	30/05/2012		In review process

(1) Intergroup study coordinated by EORTC (2) Intergroup study to which EORTC is collaborating

Between 01 January 2011 and 30 June 2012, a total of nine full protocols and four Group Specific Appendices (GSAs) were submitted for review. All four GSAs and eleven full protocols were accepted (three of which were submitted in 2010) and one remains in the review process have been accepted.

During the same period, 62 protocol amendments were approved (40 scientific and 22 administrative amendments). Of these 37 were submitted in 2011 and 25 in the first half of 2012.

Full protocol submission

Full protocols are developed in a modular way with the logistical support of the EORTC Protocol Help Desk (PHD) and the HQ team. Appropriate instructions, guidelines, and templates will be addressed to the Study Coordinator by the PHD shortly after outline approval.

When the final version of the full protocol is available, the Study Coordinator in collaboration with the HQ team should send a submission letter (or e-mail) which includes the description of eventual differences between the accepted outline and the full protocol to the PRC secretariat.

The final protocol version will be subject to an internal revision process within the HQ to check adherence with the PRC approved outline, compliance with EORTC Policies and with EORTC Standard Operating Procedures, and to detect eventual discrepancies or inconsistencies that might affect the conduct and/or the management of the study. In case of major discrepancies with the original outline and/or irresolvable disagreement with the internal reviewers, the protocol will be resubmitted to the PRC.

All Study Coordinators need to complete a conflict of interest form according to the EORTC Conflict of Interest and Confidentiality Policy and sign the document entitled 'Tasks & responsibilities of Study Coordinators'. Both documents are sent to the Study Coordinator at the time of outline approval and must be signed before submission of the full protocol.

Intergroup studies

Intergroup studies should follow the EORTC Intergroup Policy. If the trial is coordinated by an EORTC Group or HQ, EORTC approval will be obtained through the usual submission procedure (see above). If the EORTC is neither the Coordinating Group nor the Coordinating data center, the EORTC Group(s) should appoint an 'EORTC Coordinator' who will complete an outline questionnaire (even if the full protocol is already available) and send to the PRC secretariat a copy of all available documentation of prior peer reviews of the project (preferably as digital versions). If the study is already active in another group, the reasons why the EORTC will join the trial at a late stage should be explained in the comment section of the outline questionnaire. If the full protocol is already finalized, it should be sent to the PRC secretariat at the time of outline submission. If the GSA is already finalized and approved by the EORTC International Regulatory Affairs / Intergroup Office, the PRC Secretariat should be informed. Development of the full protocol is normally the responsibility of the Coordinating Group. HQ will develop a GSA. Further review process will be decided by the PRC on the basis of the information provided at the time of outline submission.

Amendments

After PRC approval, any modifications to the protocol, patient information sheet and informed consent document (PIS/IC) or GSA must be discussed and subsequently submitted or notified to the PRC, as appropriate. The changes will be reviewed, approved and implemented in the protocol, and a new version will be issued. HQ will make new versions available on the web site, circulate the amendment and the new version of the protocol to all investigators, and will inform health authorities and ethics committees when needed.

All documents and correspondence should be addressed to the EORTC PRC secretariat: prc.sec@eortc.be

The EORTC Scientific Audit Committee (SAC) gives independent advice to the EORTC Board regarding the activities and scientific output as well as overall priorities and strategies of the Divisions, Groups, and Task Forces of the EORTC. Recommendations also include criteria such as conformity with EORTC structure and policies as well as interaction with other EORTC Groups.

The SAC evaluates the effectiveness of the research programs conducted by the Groups. The SAC provides suggestions intended to strengthen the Groups and overall functioning of the EORTC. Each research group bearing the EORTC name is reviewed every three to four years. Approximately 50% of SAC members have no EORTC involvement. Its members represent a cross-section of international opinion and expertise. Members are committed to a three-year renewable term. The choice of EORTC members or non-EORTC members is revised as appropriate to avoid a lack of continuity in SAC reviews.

Chair I. Tannock, Toronto (CA)

Secretary F. Cardoso, Lisbon (PT)

Members
D. Ang Kian, Houston (US)
P. Ljungman, Stockholm (SE)
L. Cataliotti, Florence (IT)
C. Dittrich, Vienna (AT)
E. Eisenhauer, Ontario (CA)
D. Lacombe, Brussels (BE)
T. Le Chevalier, Villejuif (FR)
F. Meunier, Brussels (BE)
J.-Y. Pierga, Paris (FR)
M. Tempero, San Francisco (US)
M. Verheij, Amsterdam (NL)

Scientific Audit Committee Report 2012

In April 2012, seven groups were reviewed at the SAC meeting: the Brain Tumor, Pathobiology, Pharmacology and Molecular Mechanisms, Gastrointestinal Intestinal Tract Cancer, Genito-Urinary Cancers Group, Leukemia, and Imaging Groups. Dr. Tannock presented an executive summary of the SAC committee deliberations and recommendations to the EORTC Board at its meeting in June 2012.

The primary objective of the QAC is to work closely with all quality assurance partners from the EORTC disease oriented groups and the EORTC Headquarters Quality Assurance and Control Unit (QA&C) to ensure continuous improvement and development of forward thinking in relation to transversal quality strategies. It also stimulates transversal EORTC quality assurance initiatives such as for radiotherapy, surgery, and pathobiology. The QAC assesses serious non- compliance issues and recommends actions, as appropriate, to comply with Good Clinical Practice and new directives/ guidelines from Regulatory Authorities. Issues in which an allegation of scientific misconduct has been raised are directed to the QAC, and the follow up is coordinated by the QA&C and the QAC. The QAC reports these issues to the EORTC Board.

Chair K. Haustermans, Leuven (BE)

Secretary C. de Balincourt, Brussels (BE)

Members

L. Collette, Brussels (BE)
M. den Dulk, Leiden (NL)
B. Kasper, Mannheim (DE)
D. Lacombe, Brussels (BE)
M. Leahy, Manchester (UK)
J-P. Machiels, Brussels (BE)
F. Meunier, Brussels (BE)
P. Poortmans, Tilburg (NL)
H. van Krieken, Nijmegen (NL)
C. Schuhmacher, Munich (DE)
R. Salgado, Brussels (BE)

A permanent Independent Data Monitoring Committee (IDMC) was established in 2001 to review the status of EORTC clinical trials and make recommendations to the Groups concerning trial continuation, modification, and/or publication.

Chair A. Awada, Brussels (BE)

Members
M. Gnant, Vienna (AT)
G. Griffiths, Cardiff (UK)
A. Horwich, Sutton (UK)
K. Pritchard, Toronto (CA)
P. Scalliet, Brussels (BE)
L. Collette, Brussels (BE) *(Ex officio member)*

In accordance with EORTC POL 004, external study specific experts provide advice to the IDMC on a confidential basis.

The IDMC meets on a quarterly basis or according to need.

In 2011, nine different trials were reviewed of which four were reviewed twice. Since the beginning of 2012, the IDMC has met two times and reviewed two studies.

In March 2012 Laurence Collette took over the role of EORTC Headquarters IDMC Coordinator from Richard Sylvester, and since June 2012, Ahmad Awada is the new IDMC Chair.

IDMC review is mandatory for phase III trials where formal interim analyses and early stopping rules are foreseen and is recommended in the following situations:

- Intergroup trials coordinated by the EORTC;
- All trials requiring the randomization of more than 1000 patients or more than four years of patient accrual;
- Trials with highly toxic regimens or particular safety concerns;
- Trials encountering major strategic dilemmas (for instance, problematic issues arising from similar studies elsewhere);
- Pivotal phase III trials which will be used for drug registration;
- Randomized phase II trials that may be continued as a phase III trial without clear rules in the protocol.

The IDMC also reviews requests for the early release of data prior to trial maturity. The Committee's recommendations are forwarded to the trial management group and to the EORTC Board when further action is required.

EORTC MEMBERSHIP COMMITTEE (MC)

Chair	P. Rutkowski, Warsaw (PL)
Secretary	A. Marinus, Brussels (BE)
Members	T. Conroy, Vandoeuvre-Les-Nancy (FR) J.W. Leer, Nijmegen (NL) F. Meunier, Brussels (BE) J. Vermorken, Edegem (BE)

Membership in the EORTC is coordinated by the EORTC Membership Committee (MC). New applicants (institution / member) must submit a membership application to the MC, who then assesses the application according to the following criteria:

- track record of research of the institution / member; status of available medical facilities of the institution / member;
- availability of qualified personnel for clinical trial management of the institution / member;
- potential benefit for other EORTC institutions / members that the applying institution / member might provide.

EORTC Membership is subject to confirmation by the EORTC Board which occurs once per year and is based on a report issued by the MC in collaboration with the Chairs of the relevant EORTC Groups.

For further information regarding EORTC membership,
please contact the EORTC Membership committee: membership@eortc.be

The Institutional Review Board (IRB) of EORTC Headquarters is responsible for safeguarding the rights and welfare of subjects participating in clinical trials supported by the Headquarters. In particular, the IRB is responsible for protecting the privacy and confidentiality of the individuals' data. The IRB is responsible for the validation of the document templates for informed consent and patient information sheets. All institutions and investigators submitting data to the Headquarters agree to abide by the decisions of the IRB regarding data collection, transfer, storage, release, retention, and disposition, as these pertain to individual patient privacy and confidentiality. The IRB also reviews potential conflicts of interest reported to the Headquarters. All electronic and computer programs/software and procedures are evaluated annually in order to comply with the international requirements for patient data protection.

In addition, the EORTC IRB oversees the clinical trials performed with the United States of America cooperative groups / National Cancer Institute under the Federalwide Agreement (FWA).

Chair

A. Negrouk, Brussels (BE)

Members

F. Crawley, Leuven (BE)
Ch. de Balincourt, Brussels (BE)
C. Fortpied, Brussels (BE)
J. Geissler, Riemerling (DE)
R. Karra, Brussels (BE)
J. Otten, Brussels (BE)
P. Ruyskart, Brussels (BE)

The full text of all EORTC policies is available on the EORTC website.

- **Conflict of Interest - Confidentiality**

  Defines areas of conflict of interest and identifies when disclosure should be provided to eventually place limitations on investigators' participation in EORTC activities.

- **Protection of Human Subjects Participating in Clinical and Translational Research**

  Provides guidance on how to ensure the protection of the rights, safety, and well-being of trial subjects pertaining to all EORTC activities within the European regulatory framework.

- **Research Misconduct**

  Describes the review of research misconduct allegation and subsequent investigation and outcome.

- **Independent Data Monitoring Committee and Interim Analyses**

  Describes the EORTC policy for the use of Independent Data Monitoring Committees (IDMC) in randomized phase II and III clinical trials.

- **Intergroup Studies**

  Outlines the EORTC principles on intergroup studies involving non-EORTC groups to facilitate this type of collaboration.

- **Criteria and Guidelines for Giving the EORTC Label to Scientific Meetings**

  Describes the application, EORTC support, and contractual obligations of the applicant/organizer.

- **Scientific Audit Committee**

  Describes the responsibilities of the Scientific Audit Committee (SAC) and the process of EORTC group review.

- **Release of Data from EORTC Studies for Use in External Research Projects**

  Defines the terms and conditions under which individual data from all or a subset of the patients treated within EORTC protocols may be released to academic institutions for the purpose of scientific research projects.

- **Disclosure of Results and Publication Policy**

  Describes the policy on study publication with respect to the timing, authorship, and acknowledgement rules; review process; publication of safety, translational research of ancillary studies related to the protocol, and their authorization process; results of use of biological material from clinical studies.

- **New Drug Advisory Committee**

  Describes the missions and tasks of the New Drug Advisory Committee (NDAC) which supports and gives recommendations to the clinical research groups in new drug development within the EORTC network.

- **Translational Research Advisory Committee**

  Describes the missions and tasks of the Translational Research Advisory Committee (TRAC) and outlines the interaction between TRAC and the Translational Research Unit at EORTC Headquarters.

- **Protocol Development Process, Selection and Approval Procedures for EORTC Studies**

  Describes the milestones and criteria for selecting studies to be conducted by the EORTC and the optimal manner for submitting a study proposal to the EORTC and developing it into a protocol.

- **EORTC Principles for Investigational Sites Activation**

  Describes study specific principles and criteria with which investigational sites have to comply in order to be approved and activated.

- **Developing EORTC Guidelines, Expert Opinions, and the use of EORTC Results in Promotional Material on Cancer Care**

  Guideline regarding the structure for the development and approval of documents that are published either as EORTC Guidelines on behalf of the EORTC or EORTC Expert Opinions on behalf of an EORTC Group and the use of EORTC results in promotional material on cancer care.

- **Human Biological Material Collection, Storage and Use**

  Defines the position of the EORTC concerning the management of Human Biological Material (HBM) collected from participants enrolled in EORTC studies and projects with regards to collection storage and use. It outlines the minimal principles for both EORTC and non-EORTC parties.

The EORTC is an international association under Belgian law. The registered office of the EORTC is 83 Av. E. Mounier, B-1200 Brussels, Belgium.

The EORTC is the legal sponsor for the majority of the trials run under its auspices, except in the United States, Canada, and Australia, where trials are performed in collaboration with other partners.

The EORTC insurance program, established in 1993, covers all patients entered into EORTC studies and for which the EORTC is the sponsor/ promoter on the European continent.

For Intergroup trials lead by non-EORTC groups, sponsorship issue is discussed on a case by case basis taking into account applicable legislation. For trials fully supported fully by an industrial partner, the industrial partner is usually the sponsor.

In order to fulfill the sponsor's legal obligations and to guarantee compliance with applicable national laws, the Regulatory Affairs Unit at EORTC Headquarters keeps its legal expertise up to date in more than 30 countries in Europe and other countries.

The EORTC also plays a major role both at the European and national levels to alert regulators to the need for independent clinical research conducted without commercial aims.

Ethical aspects and informed consent/insurance

All EORTC protocols are written and conducted in accordance with international standards for ethics: the Declaration of Helsinki, Good Clinical Practice guidelines approved by the International Conference on Harmonization. A standard chapter on Ethical Considerations is included in all EORTC protocols.

In accordance with local, regional, and national requirements, written approval from competent ethics committees must be obtained before an institution is given the authorization to register or randomize a patient into a study. Standard guidelines for obtaining informed consent from patients entered in EORTC protocols have been developed. Investigators must obtain a dated and signed consent form from each patient.

All internal and external staff involved in clinical activities need to comply with EORTC policies and procedures. More specifically, investigators, Board members and Headquarters Staff must sign a conflict of interest statement.

The EORTC Network of Core Institutions (NOCI) promotes and supports high quality translational research-driven clinical trials and cooperation between the EORTC Translational Research and Clinical Research Divisions and the various EORTC Research Groups.

The principal goal of NOCI is to conduct the most challenging translational research based studies and transfer discoveries of molecular markers and genomic signatures to new medicines and tailored therapies. It is aimed at identifying the molecular determinants of activity or toxicity whether host or tumor related.

Beyond the network, NOCI is above all, a concept that optimizes and builds on the strengths and expertise of the traditional EORTC Clinical Research Groups as well as of the EORTC laboratory and translational networks. NOCI allows optimization of the scientific contribution of EORTC Groups while enhancing the knowledge and the know-how to build sophisticated clinical trial platforms. NOCI therefore provides additional opportunities to EORTC groups for new clinical research approaches.

The benefits of the NOCI concept are multifold:

- NOCI facilitates prospective tissue collection with the final objective being the establishment of storage facilities for biological materials and the uniform collection of high quality samples on a routine basis. NOCI is, therefore, a key feature to address emerging challenges with access to comprehensive clinical databases and related biological data.
- NOCI brings new insights into the EORTC scientific strategy. As the understanding of molecular biology evolves, it has become increasingly critical to model clinical research methodology and drug development approaches to take into account the role of the molecular discriminates, whether host or tumor related, to predict activity or toxicity. This is best achieved through the incorporation of translation medicine in the design of clinical trials with the ultimate goal to treat the right tumor and the right patient at the right time with the right agent. Taken together, these parameters push towards an era of personalized medicine. These changes have profound effects on the design and conduct of modern clinical research. Not only are end-points and statistical designs being revisited, but also the organization and the infrastructure for performing such trials are necessitating major upgrades. Indeed, implementing translation research, whether integrated in the design or correlative to the conduct of trials, requires access to human biological material and/ or complex molecular imaging which brings new challenges for quality assurance and standardization in multicenter clinical trials.

EORTC FELLOWSHIP PROGRAM

An EORTC Fellowship Program was established in 1991 to promote European cancer clinical research by encouraging physicians and scientists from all over the world to stay for up to three years as research fellows at EORTC Headquarters in Brussels. Medical doctors, bio-statisticians, and other scientists are eligible for this fellowship program which is specifically linked to the EORTC Groups, research program, or specific research projects undertaken by EORTC Headquarters.

EORTC Research fellowships have been awarded to 132 fellows from various European countries as well as from Argentina, Australia, Brazil, Cameroon, Canada, China, Morocco, Japan, Republic of South Korea, Turkey, Uganda and Zimbabwe.

The purpose of the fellowship program is to provide training in the methodology of clinical research for physicians and other professionals interested in cancer clinical research to complete a research project and/or PhD thesis based on data available in the EORTC databases. All research work undertaken is performed internationally. This approach also promotes the rapid diffusion of results of clinical trials.

Scientific support is provided by EORTC Headquarters staff, and supervision is provided by both EORTC Headquarters as well as members of the EORTC groups.

Support for this Fellowship Program is obtained from several sources including the Vlaamse Liga tegen Kanker, the Dutch Konigin Wilhehmina Fonds Kankerbestrijding, the Schroeder Foundation, the Melvin Seiden Foundation, and the Pfizer Foundation (within the framework of the PROBE Project). This funding program is coordinated by the EORTC Charitable Trust.

In addition to support from the EORTC, fellowships for medical doctors are also provided on ongoing basis by the Fonds Cancer / FOCA (Belgium), since 1991.

The Emmanuel van der Schueren Fellowship was created in 1999 in memory of Professor Emmanuel van der Schueren. This fellowship aims to promote research on quality assurance in radiotherapy. Currently, this program is supported by the Vlaamse Liga tegen Kanker and the EORTC.

On the occasion of the 50th Anniversary of the EORTC (March 2012), a fellowship has been allocated by Bristol Myers Squibb (BMS) to evaluate new models of partnership between academia and industry.

www.eortc.be/jobs/documents/FellowshipProgram.htm

The EORTC Headquarters Fellowship Program 1991 - 2012

Pascal Piedbois, MD	France	1991
Peter Clahsen, MD	The Netherlands	1992 - 1994
Ann Marie Ptaszynski, MD	Belgium	1992 - 1994
Sabrina Pocceschi, JD	Italy	1992 - 1996
Patrick Therasse, MD	Belgium	1993 - 1995
Magdalena Bielska-Lasota, MD	Poland	1993 - 1994
Saïd Serbouti, MS	France	1993 - 1994
Ivana Teodorovic, MD	Yugoslavia	1993 - 1993
Adam Pawinski, MD	Poland	1993 - 1995
Cristina Oliva, MD	Italy	1993 - 1994
Anne Magotteaux, MD	Belgium	1993 - 1994
Denis Lacombe, MD	France	1993 - 1996
Guido Hoctin-Boes, MD, MS	Belgium	1993 - 1995
Koen Torfs, MS	Belgium	1993 - 1993
Elke Bahner, MD	Germany	1993 - 1994
Desmond Curran, MS	Ireland	1993 - 1997
Chrisa Tsitsa, MS	Greece	1993 - 1994
Stephan Tomasovic, Pharm	Belgium	1994 - 1995
Eugenio Zabala, PhD	Spain	1994 - 1995
Channa Debruyne, MD	Belgium	1994 - 1997
Niels Neymark, MS	Denmark	1994 - 1997
Thierry Gil, MD	France	1994 - 1996
Hamdy Adham, MD	Belgium	1994 - 1995
Joszef Horti, MD	Hungary	1994 - 1996
Thierry Pignon, MD	France	1995 - 1995
Tracey Cooke, RN	United Kingdom	1995 - 1996
Susan Keating, MD	United Kingdom	1995 - 1999
Laurence Collette, MS	Belgium	1995 - 1998
Eugenio Donato di Paolo, MD	Italy	1995 - 2000
Francesco Pignatti, MD	Italy	1995 - 1996 1997 - 1998
Henk-Jan van Slooten, MD	The Netherlands	1995 - 1996
Petra J. Timmers, MD	The Netherlands	1995 - 1997
Jan Bussels, MS	Belgium	1995 - 1997
Michèle van der Heyden, MS	Belgium	1995 - 1998
Sandra Kalman, MS	Australia	1996 - 1997
Debora Goran, RGN, BSc.Hons.	United Kingdom	1996 - 1998
Ingvar Rosendahl, MSc	Sweden	1996 - 1997
Gabriele Calaminus, MD	Germany	1996 - 1997
Ines Adriaenssen	Belgium	1996 - 1999

Josée-Anne Roy, MD	Canada	1996 - 1997
Sibel Ascioglu Akhan, MD	Turkey	1996 - 1997
Sabine Steimle, MA	Germany	1997 - 1999
Simon Cleall, MSc	United Kingdom	1997 - 1998
Maryam Bigdeli, Pharm. MPH	Belgium	1997 - 1998
Lisa Tyndall	Australia	1997 - 2000
Benoît Baron, MSc	Belgium	1997 - 1998
Pieter Clahsen, MD	The Netherlands	1998 - 1998
Helena Wagenaar, MD	The Netherlands	1998 - 2000
Anastassia Anastasopoulou, MSc	Greece	1998 - 1999
Susan Caleo, Grad.Dip.Sc (Pharm)	Australia	1998 - 1999
Joannis Lainas, MSc, Pharm	Greece	1998 - 1999
Sofie Van Impe	Belgium	1998 - 2001
Catherine Legrand, MSc	Belgium	1998 - 1999
Kristel Van Steen, MSc	Belgium	1998 - 1999
Conny den Hertog-Vrieling, MD	The Netherlands	1999 - 1999
Jocelyn Kramer, MD	United Kingdom	1999 - 2000
Elizabeth Gray	Australia	1999 - 2002
Catherine Mary Roche, MA	Ireland	1999 - 2000
Jos van der Hage, MD	The Netherlands	1999 - 2000
Dritan Bejko, MD, MSc	Albania	1999 - 2000
Alfredo Zurio, MD	Italy	1999 - 2000
Thomas Roy, MSc	France	1999 - 2001
Florence Duffaud, MD	France	1999 - 2000
Sandrine Marréaud, MD	France	1999 - 1999
Griet Boon, MSc	Belgium	1999 - 2001
Nina Bijker, MD	The Netherlands	1999 - 2000
Peggy Hugo, MD	Belgium	2000 - 2001
Heidy Van Wijk, MD	The Netherlands	2000 - 2001
Xavier Paoletti, MSc	France	2000 - 2001
Liliana Baila, MD	Romania	2000 - 2001
Marlies Landheer, MD	The Netherlands	2000 - 2001
Natasa Djurasinovic, MD	Yugoslavia	2000 - 2002
Gary Stephen Collins, Msc	United Kingdom	2000 - 2002
Vassilios Kouloulias, MD	Greece	2001 - 2002
Mirella Nijmeijer, MD	The Netherlands	2001 - 2002
Fabio Efficace, PhD	Italy	2001 - 2005
Lotte Moser, MD	The Netherlands	2002 - 2003
Fatma Ataman, MD	Turkey	2002 - 2004
Koen Peeters, MD	The Netherlands	2002 - 2004
Jeremie Lebrec, MSc	France	2002 - 2002

Elçin Ozalp, MD	Turkey	2003 - 2003
Iske Florien Van Luik, MD	The Netherlands	2003 - 2004
Saidi Abdessamad, PhD	Morroco	2003 - 2003
Takuhiro Yamaguchi, PhD	Japan	2003 - 2004
Julie Francart, MSc	Belgium	2004 - 2006
Sylviane Carbonnelle, MD	Belgium	2004 - 2005
Elena Musat, MD	Romania	2004 - 2006
Hwan-Jung Yun, MD	Republic of Korea	2005 - 2007
Maria Karina, MD	Greece	2005 - 2006
Gaston Demonty, MD	Argentina	2005 - 2006
Murielle Mauer, PhD	Belgium	2006 - 2007
Alexandra Dos Santos Zimmer, MD	Brazil	2006 - 2008
Diane Van Vyve	Belgium	2006 - 2008
Tom Budiharto	Belgium	2006 - 2007
Sandra Collette	France	2007 - 2007
Carolina Claassens, MSc	The Netherlands	2007 - 2009
Monia Ouali, MSc	France	2007 - 2009
Leen Verleye, MD	Belgium	2007 - 2010
Laurent Greillier, MD	France	2007 - 2008
Oscar Matzinger	Switzerland	2008 - 2009
Francesca Bianca Martinelli, MSc	Italy	2008 - 2011
Athanasios Pallis, MD	Greece	2008 - 2009
Joh Maringwa, MSc	Zimbabwe	2008 - 2010
Gustavo Werutsky, MD	Brazil	2008 - 2011
Gloria Tridello, MSc	Italy	2009 - 2011
Agnes Czimbalmos, MD	Hungary	2009 - 2010
Paul Fenton, MD	British	2009 - 2010
Jurgen Vercauteren, MSc	Belgium	2009 - 2010
Caroline Piette, MD	Belgium	2009 - 2010
Nicolas Penel, MD	France	2009 - 2010
Ravichandra Karra, MD	India	2010 - 2010
Elizabeth Sloan, MSc	Canada	2010 - 2010
Alysa Fairchild, MD	Canada	2010 - 2011
Camilo Moulin, MD	Brazil	2010 - 2011
Erik Tanis, MD	The Netherlands	2010 - 2012
Julie Lorent, Ir	France	2010 - 2012
Zouheir Snouber, MD	Algeria	2010 - 2011
Francisco Bautista, MD	Spain	2011 - 2012
Ewane Divine Ediebah, MSc	Cameroon	2011 - 2013
Diego Reis, MD	Brazil	2011 - 2012
Leen Slaets, PhD	Belgium	2011 - 2012

Nicolas Martin, Ir	France	2011 - 2012
Mehtap Coskun, MD	Turkey	2011 - 2012
Yan Liu, MD	China	2011 - 2012
Mariano Suppa, MD	Italy	2012 - 2013
Elke-Susen Burock, MD	Germany	2012 - 2013
Fei Fei, MD	China	2012 - 2013
Jessica Menis, MD	Italy	2012 - 2013
Konstantinos Tryfonidis, MD	Greece	2012 - 2013
Warren Grant, MD	United Kingdom	2012 - 2013
Agnes Natukunda, MSc	Uganda	2012 - 2013
Elisa Rizzo, MSc	Italy	2012 - 2013

The EORTC Lady Grierson Research Fellowship Program

Ingvar Rosendahl, Ba	Sweden	1996 - 1997
Jocelyn Kramer, MD	United Kingdom	1999 - 2000
Fabio Efficace, PhD	Italy	2001 - 2002

Fellows KWF, Koningin Wilhelmina Fonds, The Netherlands

Henk-Jan van Slooten, MD	The Netherlands	1995 - 1996
Petra J. Timmers, MD	The Netherlands	1995 - 1997
Helena Wagenaar, MD	The Netherlands	1998 - 2000
Conny den Hertog-Vrieling, MD	The Netherlands	1999
Jos van der Hage, MD	The Netherlands	1999 - 2000
Marlies Landheer, MD	The Netherlands	2000 - 2001
Heidy Van Wijk, MD	The Netherlands	2000 - 2001
Mirella Nijmeijer, MD	The Netherlands	2001 - 2002
Lotte Moser, MD	The Netherlands	2002 - 2003
Iske Florien Van Luijk, MD	The Netherlands	2003 - 2004
Erik Tanis, MD	The Netherlands	2010 - 2012

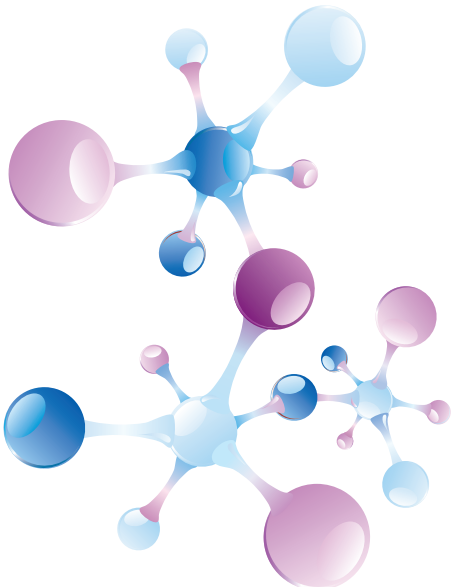
The Emmanuel Van Der Schueren Fellowship Program

Vassillios Kouloulias, MD, PhD	Greece	2001 - 2002
Fatman Ataman, MD	Turkey	2002 - 2004
Elena Musat, MD	Romania	2004 - 2005
Tom Budiharto, MD	Belgium	2006 - 2007
Oscar Matzinger, MD	Switzerland	2008 - 2009
Paul Fenton, MD	United Kingdom	2009 - 2010
Alysa Fairchild, MD	Canada	2010 - 2011
Mehtap Coskun	Turkey	2011 - 2012
Warren Grant, MD	United Kingdom	2012 - 2013

Current EORTC Fellows

Eight medical fellows (from China, Germany, Greece, Italy, The Netherlands and the United Kingdom) are currently hosted at EORTC Headquarters in the following fields: quality assurance in radiotherapy (granted by the Vlaamse Liga tegen Kanker / Emmanuel van der Schueren Fellowship), general methodology of cancer clinical trials (breast, imaging, gastro-intestinal cancer, head & neck cancer, lung cancer and melanoma), and an investigation into new approaches to integrate academia and industry towards increased R&D productivity in the next generation of public-private partnerships.

Three statistician fellows (from Cameroun, Italy and Uganda) are also at EORTC Headquarters to specialize in the field of cancer clinical trials statistics (general methodology, radiotherapy, phase I) and to work within the EORTC Quality of Life Department on the PROBE (Patient Reported Outcomes and Behavioral Evidence) research project.



Core support is crucial in the field of clinical research in oncology to pursue a strong European-wide effort with a view towards establishing state-of-the art treatment strategies on an independent basis so as to rapidly improve cancer care in Europe. Significant progress in a timely fashion will only result from international cooperation. The coordinating structure of the EORTC can be regarded as vital to harmonizing and conducting high-quality clinical and translational cancer research in Europe. As such, the EORTC deserves recognition and support at a European level as a true and established research infrastructure contributing both to EU research efforts to build a European Research Area and to the improvement of cancer management.

The EORTC has over 50 years of experience in conducting independent multinational clinical research in Europe, and this experience enabled it to make contributions to the development of Horizon 2020 and ensuring that this program will provide efficient public support for independent clinical research for the benefit and well-being of European citizens.

The EORTC does not receive any core support from the European Union. However, the EORTC has a long-standing history of participation in European Commission funded projects in the framework of the European Union research activities.

Since 1984, the EORTC has participated in more than 35 research projects funded by the European Commission in various cancer related fields including quality of life assessment, leukemia research, supportive care, telematics, biological response modifiers, pharmacokinetics, treatment costs evaluation, meta-analyses of cancer clinical studies, biomarkers, genomics, tissues banking, fellowships, and research infrastructures.

In 2005, the EORTC created the EU Program Office (EUPO) for supporting and optimizing the EORTC participation in European institutional activities as well as to raise the visibility of the EORTC within the European arena. The EUPO mission is mainly to support the preparation of proposals for EU projects and to coordinate and support EORTC participation in EU funded projects. During the past six years, 76 projects involving EORTC were discussed, 48 finally submitted and 16 funded.

Current EORTC participation in FP7 involves the following EU Funded Projects:

- the Network of Excellence **EurocanPlatform** (A European Platform for Translational Cancer Research),
- **EUROSARC** (European Clinical trials in Rare Sarcomas within an integrated translational trial network).

As an established international clinical research infrastructure, the EORTC is playing a pivotal role linking two ESFRI (European Research Infrastructure) projects:

- **ECRIN-IA** (European Clinical Research Infrastructures network and biotherapy facilities- Integrated Activities),
- **Euro-BioImaging** (European Biomedical Imaging Infrastructure, the preparatory phase of an ESFRI Research infrastructure).

The EORTC is co leading an Innovative Medicine Initiative (IMI) project:

- **QUIC-CONCEPT** (Quantitative Imaging in Cancer: Connecting Cellular Processes with Therapy).

EORTC is also highly involved in the IMI program:

- **PharmaTrain** (Pharmaceutical Medicine Training Programs),
- **EUPATI** (European Patients' Academy on Therapeutic Innovation).

The EORTC has received a grant from the DG Health and Consumers for organizing an international conference "Quality of Life and Symptom Research in Cancer Clinical Trials" in October 2012.

The European Directive 2001/20/EC on Clinical trials was implemented in 2004 by the Member States. Since the first discussions around the directive in the late 1990's, the EORTC has been interacting with both European and national authorities to address specific issues related to the implementation of the Directive in the context of non-commercial research. As academic sponsor of international clinical trials, the EORTC has been successful in positioning itself as a unique and internationally recognized clinical research organization whose opinion is highly valued, and, in close collaboration of DG Health and Consumers and DG Research and Innovation, is now at the forefront of the multi-stakeholder discussions for improving the regulatory and legal environment but also the funding perspectives for independent clinical research in Europe. EORTC jointly or co-organized several meetings and workshops set-up by the European commission, regulatory authorities, the Federation of European Academies of Medicine (FEAM), the European Forum for Good Clinical Practice (EFGCP), the European Science Foundation (ESF) and other organizations. As a result, a proposal for a new regulation has been submitted by DG Sanco to the European Parlement.

The National Cancer Institute (NCI) is the leading US agency for cancer research and treatment in the United States and is part of the National Institutes of Health (NIH). The NCI was established by the US Congress in 1937, and its programs were intensified in 1971 after passage of the National Cancer Act. The vast majority of NCI funds (80%) goes to grants and contracts to universities, medical schools, cancer centers, research laboratories and private firms. The NCI supports scientists all over the world in a broad spectrum of research activities.

The recently created NCI Center for Global Health (CGH) supports NCI's goal to advance global cancer research, build expertise, and leverage resources across nations to address the challenges of cancer and reduce cancer deaths worldwide. Enabling the open exchange of scientific knowledge is a critical goal in the fight against cancer. The CGH facilitates research efforts to decrease the global burden of cancer by collaborating with U.S. government agencies, foreign governments, non-government organizations, and pharmaceutical and biotechnology companies. The primary functions of the CGH will be to:

- Develop and implement plans to inform cancer control, and provide technical assistance as countries work to implement cancer control programs;
- Strengthen U.S. national, regional, multilateral, and bilateral collaboration in global health research, cancer research, and cancer control;
- Train investigators and help develop research capacity in global health across the cancer continuum, both in the United States and in the developing world;
- Develop and validate new agents and devices for cancer prevention, screening, treatment, and symptom management appropriate for use in the developing world;
- Develop new scientific initiatives and implement plans relevant to global health and cancer control.

European-NCI Collaborative Activities

A history of more than three decades of coordinated cancer treatment research between the EORTC and the NCI has brought great opportunities for more efficient development of new cancer therapeutics.

A European Collaborative Program initiated with the EORTC in the early 70's continues to be highly successful in promoting the exchange of information on new drugs for both pre-clinical and clinical evaluation. The compound acquisition, selection, screening, formulation, toxicology, and the clinical evaluation are now well integrated between Europe and the USA. Much of this success in new drug development has been facilitated by the close working relationship between the NCI, the EORTC, and the British Cancer Research United Kingdom (CR-UK).

Clinical trials

The NCI has supported cancer research worldwide for decades, but international collaboration on clinical trials requires that a number of administrative issues are addressed to satisfy the requirements of both the NCI and its partners. Top issues on the list include working out trial sponsorship (particularly for US/EU trials, where the EU Clinical Trial Directive mandates a single European Sponsor), arranging drug supply both in the US and for partner sites abroad (with regard to EU, the QP

(qualified person) process and labeling requirements must be satisfied), establishing agreements with partner research networks and with any pharmaceutical companies involved (in particular, issues about database access and intellectual property rights). The NCI and its international partners have managed to overcome these and other administrative barriers and have succeeded in conducting truly collaborative trials - not just parallel studies, but full partnerships with a single, joint protocol.

This sort of collaboration is especially important in the accrual of patients to trials focused on very rare cancers (see below). For a number of years, US Cooperative Cancer Clinical Trial Groups, which are funded by NCI, have performed trials in brain cancer in collaboration with the EORTC. The US Groups and EORTC are now also running an ambitious 900+ patient trial in adjuvant pancreatic cancer. There have been several trials in which the US groups have collaborated with either academic or commercial Sponsors in Europe as well, including a number of pediatric studies of rare cancers (e.g. the EURAMOS study of osteosarcoma), and many other examples exist.

The International Rare Cancers Initiative (IRCI)

The IRCI was established early in 2011 and is a joint initiative between the National Cancer Institute (NCI) in the US, the EORTC, the National Institute for Health Research (NIHR) Cancer Research Network (NCRN), and CR-UK.

The objective of this initiative is to facilitate the development of international clinical trials for patients with rare cancers in order to boost the progress of new treatments for these patients. The initiative hopes to encourage the use of innovative methodologies to maximize the potential for answering research questions and to identify and overcome barriers to international trials to allow agreed IRCI trials to run smoothly.

The NCI-CGH Liaison Office

As part of the NCI's global strategy, the NCI Liaison Office in Brussels was created in 1972, to search for potential new anticancer substances from European sources. The Office expanded quickly and has been pivotal in moving Europe and North America closer to a common linked network. Situated adjacent to the EORTC headquarters, the office is part of NCI's CGH and acts as a European-based link to the NCI's cancer research and treatment programs. It facilitates the interchange of information, ideas, experimental drugs, scientific expertise and scientists between the European Region and the US NCI. Its role is to help create a network of cancer experts and cancer centers which work towards a common goal, to enable rapid progress in cancer research on an international scale. The Office also assists other NCI divisions and programs with their European activities.

Joint International Meetings

The NCI and EORTC jointly sponsor several prominent international meetings, e.g. the Molecular Targets and Cancer Therapeutics Meeting in association with AACR, an event which brings together more than 2,000 academics, scientists and pharmaceutical industry representatives from across the globe to discuss innovations in drug development, target selection and the impact of new discoveries in molecular biology. The annual Molecular Markers in Cancer Meeting in association with ASCO brings together clinicians, pathologists, researchers, and others to accelerate progress in the rapidly advancing field of cancer markers. Both meetings represent unique platforms for discussion and international networking.

Telesynergy® Medical Consultation Workstation

The NCI CGH Liaison Office is the European hub for NCI's TELESYNERGY® Medical Consultation WorkStation. The Telesynergy® Workstation allows numerous research collaborators at greatly separated geographic sites to interact as if they were in the same room, viewing the same medical images. By integrating powerful telecommunications technology into healthcare research and delivery, telemedicine enables clinical researchers to simultaneously communicate and view and manipulate data necessary for collaborations, including patient diagnosis and care, such as x-ray films and pathology samples. The telemedicine system has high quality, multi-site teleconferencing capabilities, and is also capable of transmitting most types of diagnostic-quality medical images and information from several different sources, such as a microscope, a patient examination camera, document camera, color video printer, DVD player/recorder, and PC applications.

By making the knowledge and experience of oncology experts accessible regardless of where in the world those experts are, TELESYNERGY® has the potential to dramatically accelerate cancer research and improve cancer care by facilitating unique collaborations and connections.

Among other collaborators, the European School of Oncology (ESO) makes use of the system for their live webcasts/e-grandrounds. The TELESYNERGY® Workstation is available at no cost to outside collaborators. Interested parties are welcome to use it.

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The European Joural of Cancer (EJC), the official journal of the European Organisation for Research and Treatment of Cancer (EORTC), the European CanCer Organisation (ECCO), the the European Association for Cancer Research (EACR) and the European Society of Breast Cancer Specialists (EUSOMA), is an international multidisciplinary oncology journal which publishes Original Research articles, Review articles, Editorials and Letters to the Editor on preclinical and basic science, translational oncology, clinical oncology, and epidemiology and prevention. Under the leadership of Editor-in-Chief Alexander M.M. Eggermont (Institut Gustave Roussy, France), the journal is guided by a team of Editors who are internationally recognized experts in their fields.

Impact factor

The EJC's current Impact Factor, which measures citations made in 2011 to articles published in 2009 and 2010, is 5.536. This ranks the journal in the top 25% of all oncology journals in the Journal Citation Reports (information courtesy of Thomson Reuters).

Circulation and readership

The EJC is published in print, online and has its own iPad application. More than 9 000 institutions and individuals around the world have access either in print or online, whilst more 3,500 individuals use the journal's iPad app. Over the last 12 months, 87 000 articles per month have been downloaded from the journal.

Popular papers

The five most well read articles from the EJC over the last 12 months include papers on epidemiology and cancer prevention, as well as clinical guidelines developed by the EORTC.

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EORTC Network

CLINICAL RESEARCH DIVISION GROUPS / TASK FORCES	CHAIR	SECRETARY
Brain Tumor Group	W. Wick Heidelberg (DE)	B.G. Baumert Maastricht (NL)
Breast Cancer Group	D. Cameron Edinburgh (UK)	F. Cardoso Lisbon (PT)
Children's Leukemia Group	Y. Benoit Gent (BE)	G. Plat Toulouse (FR)
Gastrointestinal Tract Cancer Group	A. Roth Geneva (CH)	M. Ducreux Villejuif (FR)
Genito-Urinary Cancers Group	B. Tombal Brussels (BE)	*To be appointed*
Gynecological Cancer Group	A. Casado Herraez Madrid (ES)	P. Ottevanger Nijmegen (NL)
Head and Neck Cancer Group	L. Licitra Milano (IT)	R. Knecht Hamburg (DE)
Infectious Diseases Group	P. Donnelly Nijmegen (NL)	M. Bassetti Genova (IT)
Leukemia Group	J-P. Marie Paris (FR)	F. Baron Liège (BE)
Lung Cancer Group	M. O'Brien Sutton (UK)	V. Surmont Gent (BE)
Lymphoma Group	R. Van Der Maazen Nijmegen (NL)	P. Meijnders Antwerp (BE)
Melanoma Group	A. Testori Milano (IT)	C. Robert Villejuif (FR)
Quality of Life Group	M. Groenvold Copenhagen (DK)	F. Efficace Rome (IT) S. Singer Leipzig (DE)
Radiation Oncology Group	P. Maingon Dijon (FR)	P. Poortmans Tillburg (NL)
Soft Tissue and Bone Sarcoma Group	W. van der Graaf Nijmegen (NL)	A. Gronchi Milan (IT)
Cancer in the Elderly Task Force	H. Wildiers Leuven (BE)	E. Brain Saint-Cloud (FR)
Cutaneous Lymphoma Task Force	R. Stadler Minden (DE)	P. Quaglino Turin (IT)
Endocrine Tumors Task Force	M. Schlumberger Villejuif (FR)	L. Licitra Milano (IT)

TRANSLATIONAL RESEARCH DIVISION GROUPS	CHAIR	SECRETARY
Imaging Group	N. deSouza Sutton (UK)	N. Nestle Freiburg (DE)
Pathobiology Group	J. Martens Rotterdam (NL)	J. Dittmer Halle (DE)
Pharmacology and Molecular Mechanisms Group	G. Peters Amsterdam (NL)	E. Raymond Paris (FR)

Total accrual of patients in EORTC clinical studies in 2000 - 2011: 71 905 patients

European Union:
64 632 patients (89,89%)

Austria	810
Belgium	7399
Bulgaria	49
Cyprus	73
Czech Republic	160
Denmark	529
Estonia	7
Finland	34
France	14438
Germany	6310
Greece	48
Hungary	210
Italy	6553
Latvia	34
Luxemburg	9
Malta	20
Poland	1082
Portugal	635
Republic of Ireland	90
Romania	20
Slovak Republic	451
Slovenia	310
Spain	2867
Sweden	595
The Netherlands	15279
United Kingdom	6620

Non-EU Countries:
3 332 patients (4.63%)

Bosnia	8
Croatia	352
Macedonia	6
Norway	454
Russia	178
Serbia	261
Switzerland	1438
Turkey	631
Ukraine	4

Rest of the World:
3 941 patients (5.48%)

Argentina	92
Australia	724
Brazil	18
Canada	855
Chile	102
Colombia	9
Ecuador	20
Egypt	334
Hong-Kong	13
India	8
Israel	443
Japan	94
Lebanon	14
Malaysia	1
Mexico	11
New Zealand	66
Pakistan	4
Peru	82
Philippines	14
Saudi Arabia	15
Singapore	16
South Africa	70
South Korea	34
Taiwan	141
Thailand	5
U. A. Emirates	2
United States of America	754

A number of EORTC trials are conducted in collaboration with other clinical cancer research groups in Europe and also on other continents. These groups provide a complementary portfolio of cancer clinical trial to the EORTC Network and bring a valuable contribution to the recruitment within EORTC intergroup trials.

EORTC Groups / Task Forces	Total 2000-2011
EORTC Brain Tumor Group	3507
EORTC Breast Cancer Group	12061
EORTC Children's Leukemia Group	1987
EORTC Cutaneous Lymphoma Task Force	154
EORTC Gastrointestinal Tract Cancer Group	2996
EORTC Genito-Urinary Cancers Group	6097
EORTC Gynecological Cancer Group	3130
EORTC Head and Neck Cancer	557
EORTC Infectious Diseases Group	957
EORTC Leukemia Group	2692
EORTC Lung Cancer Group	2060
EORTC Lymphoma Group	1869
EORTC Melanoma Group	4569
EORTC Quality of Life Group	1593
EORTC Radiation Oncology Group	9484
EORTC Soft Tissue and Bone Sarcoma Group	4093

Intergroup Collaboration

Nowadays, many cancer research groups conduct clinical trials, and within this framework closer collaboration between research groups is essential to minimize the number of competitive trials and to accrue large numbers of patients in a minimum period of time. These collaborative clinical trials are called 'Intergroup' trials.

In order to guarantee the quality of these trials and to facilitate their coordination and logistics, the EORTC has developed procedures and templates specific to this type of trials. These documents were made taking into account the legal requirements in Europe but also the policies of major cancer research groups outside Europe (such as NCI policies). Following these policies, all groups within a trial use the same protocol, the same set of CRFs, and a central database which is the first guarantee for consistency of results.

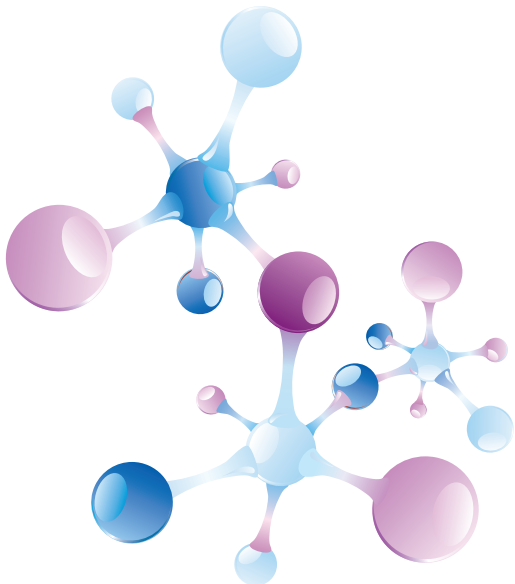
The data from all collaborating groups are centrally managed for consistent update and validation process.

Apart from the centralization of data, the coordinating center ensures the coordination of the trial logistics and legal aspects. This coordinating role is essential within the new legal framework in the EU. The EU lead group shall, among other tasks, ensure that request of EudraCT number, completion of the clinical trial application form and the reporting to the EUDRAVIGILANCE database are taken care of centrally.

Responsibilities are discussed on a trial-by-trial basis and fixed through written agreements between all involved partners. A Steering Committee composed of representatives from all participating groups decides on the scientific content of the trial and possible future use made of the material, data, and results. These policies have been applied by the EORTC for several years and have resulted in an important number of collaborations with many European and overseas cancer clinical research groups.

During 2011, there were a total of 21 ongoing intergroup trials of which eleven were coordinated by EORTC Headquarters; the remaining ten trials were coordinated by other groups. Four of these trials were run in cooperation with US collaborative groups (two as leading and two as collaborating group). Within the framework of these 21 trials, EORTC directly collaborated with 33 other networks of which 23 were from Europe, five from the United States, two from Canada, and three from Australia. Of the 23 European Networks, five were in Italy, five in the United Kingdom, five in France, two in the Netherlands, two in Germany, two in Spain, and two international.

Also in 2011, the EORTC joined forces with Cancer Research UK, the National Institute for Health Research Cancer Research Network (NCRN), and the United States National Cancer Institute (NCI) to launch an intergroup initiative to boost the development of new treatments for patients with rare cancers. This International Rare Cancers Initiative (IRCI) will design and fund clinical trials of treatments for rare cancers – defined as those which occur in approximately fewer than two cases per 100,000 people. There are limited treatment options for patients suffering with these cancers, and there is an urgent need to develop new therapies.



Contribution by non-EORTC groups to EORTC Trials in 2011

Groups contributing with more than 100 patients
Borstkanker Onderzoeksgroup Nederland
Federation Nationale des Centres de Lutte Contre le Cancer
Arbeitsgemeinschaft Internistische Onkologie
West German Study Group
Grupo espanol de estudio, tratamiento y otras estrategias ex
Gruppo Oncologico Italiano Ricercia Clinica
Industry

Groups contributing between 20 & 100 patients
Groupe d'Etudes des Lymphomes de l'Adulte
Medical Research Council
Intergruppo Italiano Linfomi
National Cancer Research Institute - Breast Cancer Group
Australasian Gastro-Intestinal Trials Group
Radiation Therapy Oncology Group
Cooperative Trials Group for Neuro-Oncology
Gruppo Italiano Malattie Ematologiche dell'Adulto
Federation Francophone de Cancerologie Digestive

Groups contributing with less than 20 patients
Hemato-Oncologie Volwassenen Nederland
Belgian Group of Digestive Oncology
French Acute Lymphoblatic Leukemia
SI_IOL
National Cancer Institute of Canada-Clinical Trial Group
Sarcoma Alliance for Research through Collaboration
Canadian Urologic Oncology Group

The EORTC has established criteria to grant recognition to Institutions/Departments actively participating in EORTC clinical trials. This list of Institutions/Departments is updated on a yearly basis. An Institution can either be granted recognition as an "EORTC Affiliated Institution" or as an "EORTC Affiliated Department".

The criteria used to merit that recognition are:

EORTC Affiliated Institution:

1. Recruitment of 75 patients over a period of three years with a minimum of 15 patients entered in EORTC clinical trials per year.
2. Participation in at least three EORTC Groups.

EORTC Affiliated Department:

3. Recruitment of 75 patients over a period of three years with a minimum of 15 patients entered in EORTC clinical trials per year.
4. Participation in less than three EORTC Groups.

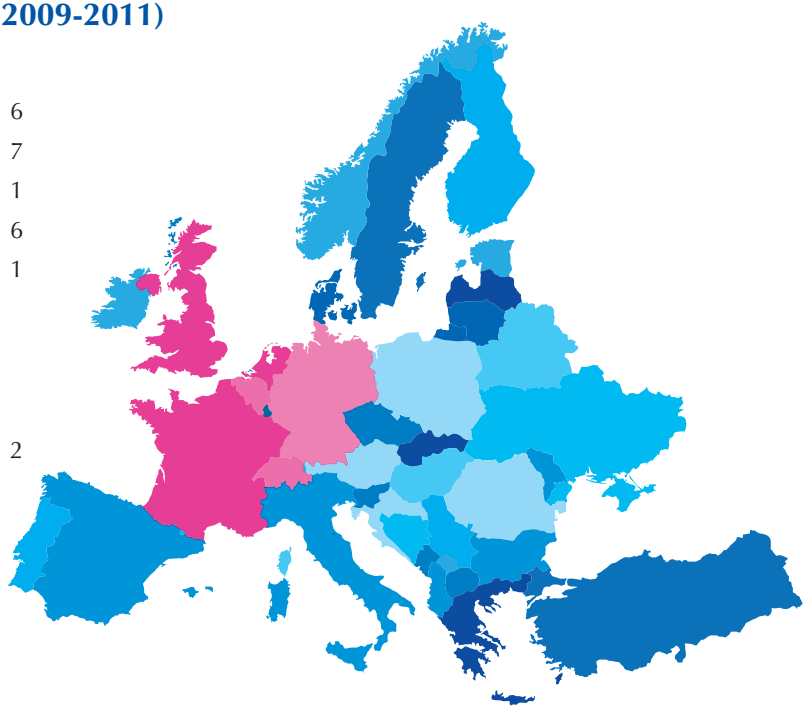
EORTC Affiliated Institutions per Country 2012 (Review period 2009-2011)

European Union:

- Belgium 6
- France 7
- Germany 1
- The Netherlands 6
- United Kingdom 1

Non-EU countries

- Switzerland 2



Ranking of EORTC Affiliated Institutions in 2012 (Review period 2009 - 2011)

The following institutions have been recognized in 2012 as EORTC affiliated institutions based on their participation in EORTC studies over the last three years.

Rank	Institution	Country	Number of EORTC Groups	Accrual 2009 - 2011
1	Institut Curie, Paris & Saint-Cloud	France	4	757
2	Institut Gustave Roussy, Villejuif	France	9	616
3	The Netherlands Cancer Institute Antoni Van Leeuwenhoekzieke, Amsterdam	The Netherlands	6	440
4	Clinique Sainte Elisabeth, Namur	Belgium	3	328
5	Hopitaux Universitaires Bordet-Erasme, Brussels	Belgium	6	301
6	Centre Georges-Francois-Leclerc, Dijon	France	4	250
7	UZ Leuven, Leuven	Belgium	10	177
8	Leiden University Medical Centre, Leiden	The Netherlands	8	162
9	Universitaetsklinikum Heidelberg, Heidelberg	Germany	3	160
10	Christie NHS Foundation Trust, Manchester	United Kingdom	5	157
11	Centre Leon Berard, Lyon	France	6	156
12	Universitaetsspital, Zurich	Switzerland	4	155
13	Arnhem 'S Radiotherapeutisch Instituut, Arnhem & Harderwijk	The Netherlands	3	152
14	UZ Rotterdam, Rotterdam	The Netherlands	7	150
15	Medisch Centrum Haaglanden, Den Haag & Leidschendam	The Netherlands	4	136
16	Centre Hospitalier Universitaire Vaudois, Lausanne	Switzerland	7	135
17	Institut Bergonie, Bordeaux	France	6	126
18	Centre Alexis Vautrin, Vandoeuvre-Les-Nancy	France	3	122
19	Radboud University Nijmegen Medical Centre, Nijmegen	The Netherlands	9	120
20	Hopital De Jolimont, Haine St Paul	Belgium	3	119
21	Cliniques Universitaires St. Luc, Brussels	Belgium	6	107
22	Assistance Publique Hôpitaux de Marseille, Marseille	France	5	99
23	H. Hartziekenhuis, Roeselare	Belgium	4	97

Ranking of EORTC Affiliated Departments in 2012 (Review period 2009 - 2011)

The following institutions have been recognized in 2012 as EORTC affiliated departments based on their participation in EORTC studies over the last three years.

Rank	Institution	Country	Number of EORTC Groups	Accrual 2009 - 2011
1	Centre Regional Francois Baclesse, Caen	France	2	214
2	Ospedale Bellaria, Bologna	Italy	2	113
3	Onze Lieve Vrouw Ziekenhuis, Aalst	Belgium	2	109
4	Onze Lieve Vrouw Gasthuis, Amsterdam	The Netherlands	2	109
5	Chu Pitie-Salpetriere AP-HP, Paris	France	2	86
6	Klinikum Der J.W. Goethe Universitaet, Frankfurt Am Main	Germany	2	80

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EORTC Current Research & Strategies

Updated information on all ongoing EORTC Protocols is available on the EORTC website: http://www.eortc.org/clinical-trials

For all EORTC Protocols, patients can be randomized online at the EORTC website: http://orta.eortc.be/

Number	Title	Target accrual
	EORTC Brain Tumor Group	
22042 **26042**	Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma : a Phase II and observation study Study Coordinator: • Damien Weber, Hôpitaux Universitaires de Genève - HUG - site de Cluse-Roseraie, Geneve	**54**
26053 **22054**	Phase III trial on concurrent and adjuvant temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma. The CATNON intergroup trial. Study Coordinators: • Brigitta Baumert, Maastro Clinic - Maastricht Radiation Oncology, Maastricht • Martin J. van den Bent, Erasmus MC - Daniel den Hoed Cancer Center, Rotterdam	**748**
26062 **22061**	A randomized phase III study of Temozolomide and short-course radiation versus short-course radiation alone in the treatment of newly diagnosed glioblastoma multiforme in elderly patients Study Coordinator: • Alba Brandes, Ospedale Bellaria, Bologna	**560**
26081 **22086**	Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with Newly Diagnosed Anaplastic Oligodendroglioma or Anaplastic Mixed Glioma with Chromosomal Co-delections of 1p and 19q. Study Coordinators: • Frederic Dhermain, Institut Gustave Roussy, Villejuif • Martin J. van den Bent, Erasmus MC - Daniel den Hoed Cancer Center, Rotterdam • Wolfgang Wick, UniversitaetsKlinikum Heidelberg - Head Hospital, Heidelberg	**585**
26082 **22081**	Radiation therapy and concurrent plus adjuvant Temsirolimus (CCI-779) versus chemo-irradiation with temozolomide in newly diagnosed glioblastoma without methylation of the MGMT gene promoter - a randomized multicenter, open-label, Phase II study. Study Coordinator: • Wolfgang Wick, UniversitaetsKlinikum Heidelberg - Head Hospital, Heidelberg	**108**

26091	Randomized trial assessing the significance of Bevacizumab in recurrent grade II and Grade III gliomas. The TAVAREC trial. Study Coordinator: • Martin J. van den Bent, Erasmus MC - Daniel den Hoed Cancer Center, Rotterdam	**144**
26101	Phase II trial exploring the sequence of bevacizumab and lomustine in patients with first recurrence of a glioblastoma. Study Coordinator: • Wolfgang Wick, UniversitaetsKlinikum Heidelberg - Head Hospital, Heidelberg	**249**
EORTC Breast Cancer Group		
10054 LAPATAX	A phase I-II study of Lapatinib and Docetaxel as neoadjuvant treatment for locally advanced breast cancer. Study Coordinators: • Herve Bonnefoi, Institut Bergonie, Bordeaux • David Cameron, Western General Hospital, Edinburgh	**114**
10085 Male BC	Clinical and biological characterization of Male Breast Cancer : an international retrospective EORTC, BIG and NABCG intergroup study. Study Coordinator: • Fatima Cardoso, Champalimaud Cancer Center, Lisboa	**1800**
10112 Aphinity	A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer. Study Coordinator: • Fatima Cardoso, Champalimaud Cancer Center, Lisboa	**3806**
22051 10052	Selective Use of Postoperative Radiotherapy AftEr MastectOmy (SUPREMO) Study Coordinator: • Geertjan Van Tienhoven, Academisch Medisch Centrum - Universiteit van Amsterdam, Amsterdam	**1600**
22085 10083	A randomized phase III study of radiation doses and fractionation schedules for ductal carcinoma in situ (DCIS) of the breast. Study Coordinator: • Helen Westenberg, Arnhem 'S Radiotherapeutisch Instituut, Arnhem	**610**

EORTC Children's Leukemia Group		
58051 Interfant	International collaborative treatment protocol for infants under one year with acute lymphoblastic or biphenotypic leukemia Study Coordinator: • Alice Ferster, Hopital Universitaire Des Enfants Reine Fabiola, Brussels	**445**
58081	Translational research - observational study for identification of new possible prognostic factors and future therapeutic targets in children with acute lymphoblastic leukaemia (ALL). Study Coordinator: • Helene Cave, Hopital Robert Debre AP-HP, Paris	**800**
58LAE	Assessment of the long term outcome of childhood ALL patients enrolled in EORTC CLG trials between 1971 and 1998 Study Coordinator: • Caroline Piette, Centre Hospitalier Regional De La Citadelle, Liege	**3138**
EORTC Cutaneous Lymphoma Task Force		
21081	A phase III study of lenalidomide maintenance after debulking with gemcitabine or liposomal doxorubicin +/- radiotherapy in patients with advanced cutaneous T-cell lymphoma not previously treated with intravenous chemotherapy Study Coordinator: • Martine Bagot, Hopital Saint-Louis AP-HP, Paris	**105**
EORTC Gastrointestinal Tract Cancer Group		
40071	Effectiveness of first line treatment with lapatinib and ECF/X in histologically proven adenocarcinoma of the stomach or the esophagogastric junction, metastatic or not amenable to curative surgery according to HER2 and EGFR status: a randomized phase II trial. Study Coordinator: • Arnaud Roth, Hôpitaux universitaires de Genève - HUG - site de Cluse-Roseraie, Geneve	**192**
EORTC Genito-Urinary Cancers Group		
22043 30041	Immediate or early salvage post-operative external radiotherapy combined with concomitant and adjuvant hormonal treatment versus immediate or early salvage post-operative external radiotherapy alone in pT3a-b R0-1 cNOMO/pT2R1 cN0M0, Gleason score 5-10 prostatic carcinoma. A phase III study. Study Coordinators: • Michel Bolla, CHU de Grenoble - La Tronche - Hôpital A. Michallon, Grenoble • Steven Joniau, U.Z. Leuven - Campus Gasthuisberg, Leuven	**600**

30072 SORCE	A Phase III Randomised Double-blind Study Comparing Sorafenib With Placebo In Patients With Resected Primary Renal Cell Carcinoma at High or Intermediate Risk of Relapse Study Coordinators: • Steven Joniau, U.Z. Leuven - Campus Gasthuisberg, Leuven • Peter Mulders, Radboud University Nijmegen Medical Centre, Nijmegen	**1656**
30073 SURTIME	Randomized Phase III trial comparing immediate versus deferred nephrectomy in patients with synchronous metastatic renal cell carcinoma. Study Coordinators: • Axel Bex, The Netherlands Cancer Institute-Antoni Van Leeuwenhoekziekenhuis, Amsterdam • John B.A.G. Haanen, The Netherlands Cancer Institute-Antoni Van Leeuwenhoekziekenhuis, Amsterdam	**458**
EORTC Gynecological Cancer Group		
55092	Phase IB-II, open label, multicentre feasibility study of Pazopanib in combination with Paclitaxel and Carboplatin in patients with platinum-refractory/resistant ovarian, fallopian tube or peritoneal carcinoma. Study Coordinator: • Ignace Vergote, U.Z. Leuven - Campus Gasthuisberg, Leuven	**36**
55102 ENGOT-EN2-DGCG/ EORTC55102	A phase III Trial of postoperative chemotherapy or no further treatment for patients with stage I-II medium or high risk endometrial cancer. Study Coordinators: • Frederic Amant, U.Z. Leuven - Campus Gasthuisberg, Leuven • Mansoor Raza Mirza, Rigshospitalet, Copenhagen	**678**
55994	Randomized phase III study of neoadjuvant chemotherapy followed by surgery vs. concomitant radiotherapy and chemotherapy in FIGO Ib2, IIa > 4 cm or IIb cervical cancer. Study Coordinators: • Alessandro Colombo, Ospedale Alessandro Manzoni, Lecco • Stefano Greggi, Istituto Nazionale Per Lo Studio E La Cura Dei Tumori, Napoli • Gemma Kenter, Academisch Medisch Centrum - Universiteit van Amsterdam, Amsterdam • Fabio Landoni, Istituto Europeo Di Oncologia, Milano	**686**
EORTC Head and Neck Cancer Group		
90111 24111	Neoadjuvant afatinib based treatment strategies followed by surgery in squamous cell carcinoma of the head and neck: an EORTC NOCI-HNCG window study Study Coordinator: • Jean-Pascal Machiels, Cliniques Universitaires St. Luc, Brussels	**30**

EORTC Infectious Diseases Group		
65091 06093	Empirical versus pre-emptive (diagnostic-driven) antifungal therapy of patients treated for haematological malignancies or receiving an allogeneic stem cell transplant. A therapeutic open label phase III strategy study of the EORTC Infectious Diseases and Leukemia Groups Study Coordinator: • Peter Donnelly, Radboud University Nijmegen Medical Centre, Nijmegen	**556**
EORTC Leukemia Group		
06031 AML-19	Gemtuzumab ozogamicin (GO) monotherapy versus standard supportive care for previously untreated AML in elderly patients who are not eligible for intensive chemotherapy : a randomized phase II/III trial (AML-19) of the EORTC-LG and GIMEMA-ALWP. Study Coordinator: • Sergio Amadori, Azienda Ospedallera Universitaria - Policlinico Tor Vergata, Roma	**260**
06061 AML-14A	Clofarabine in combination with a standard remissioninduction regimen (AraC and idarubicin) in patients 18-60 years old with previously untreated intermediate and bad risk acute myelogenous leukemia (AML) or high risk myelodysplasia (MDS) : a phase I-II study of the EORTC-LG and GIMEMA (AML-14A trial) Study Coordinators: • G. Meloni, Universita Degli Studi "la Sapienza", Roma • Dominik Selleslag, A.Z. St. Jan, Brugge • Roel Willemze, Leiden University Medical Centre, Leiden	**90**
06083 HOVON 100 ALL	Clofarabine added to prephase and consolidation therapy in acute lymphoblastic leukemia in adults. A prospective randomized trial. Study Coordinator: • Jean-Pierre Marie, Hopital Saint Antoine AP-HP, Paris	
65091 06093	Empirical versus pre-emptive (diagnostic-driven) antifungal therapy of patients treated for haematological malignancies or receiving an allogeneic stem cell transplant. A therapeutic open label phase III strategy study of the EORTC Infectious Diseases and Leukemia Groups Study Coordinator: • Peter Donnelly, Radboud University Nijmegen Medical Centre, Nijmegen	**556**

EORTC Lung Cancer Group		
08072 **22074**	Concurrent once-daily versus twice-daily radiotherapy : A 2-arm randomised controlled trial of concurrent chemo-radiotherapy comparing twice-daily and once-daily radiotherapy schedules in patients with limited stage small cell lung cancer (SCLC) and good performance status (CONVERT). Study Coordinator: • Corinne Faivre-Finn, Christie NHS Foundation Trust, Manchester	**532**
08092 **MAPPING**	Double blind randomized phase III study of maintenance Pazopanib versus placebo in NSCLC patients non progressive after first line chemotherapy. Study Coordinator: • Mary O'Brien, Royal Marsden Hospital - Sutton, Surrey, Sutton	**587**
EORTC Network of Core Institutions		
90101 **CREATE**	Cross-tumoral Phase 2 clinical trial exploring crizotinib (PF-02341066) in patients with advanced tumors induced by causal alterations of ALK and/or MET ("CREATE") Study Coordinator: • Patrick Schöffski, U.Z. Leuven - Campus Gasthuisberg, Leuven	**582**
90111 **24111**	Neoadjuvant afatinib based treatment strategies followed by surgery in squamous cell carcinoma of the head and neck: an EORTC NOCI-HNCG window study Study Coordinator: • Jean-Pascal Machiels, Cliniques Universitaires St. Luc, Brussels	**30**
EORTC Radiation Oncology Group		
08072 **22074**	Concurrent once-daily versus twice-daily radiotherapy : A 2-arm randomised controlled trial of concurrent chemo-radiotherapy comparing twice-daily and once-daily radiotherapy schedules in patients with limited stage small cell lung cancer (SCLC) and good performance status (CONVERT). Study Coordinator: • Corinne Faivre-Finn, Christie NHS Foundation Trust, Manchester	**532**
22042 **26042**	Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma : a Phase II and observation study Study Coordinator: • Damien Weber, Hôpitaux universitaires de Genève - HUG - site de Cluse-Roseraie, Geneve	**54**

22043 **30041**	Immediate or early salvage post-operative external radiotherapy combined with concomitant and adjuvant hormonal treatment versus immediate or early salvage post-operative external radiotherapy alone in pT3a-b R0-1 cNOMO/pT2R1 cN0M0, Gleason score 5-10 prostatic carcinoma. A phase III study. Study Coordinators: • Michel Bolla, CHU de Grenoble - La Tronche - Hôpital A. Michallon, Grenoble • Steven Joniau, U.Z. Leuven - Campus Gasthuisberg, Leuven	**600**
22051 **10052**	Selective Use of Postoperative Radiotherapy AftEr MastectOmy (SUPREMO) Study Coordinator: • Geertjan Van Tienhoven, Academisch Medisch Centrum - Universiteit van Amsterdam, Amsterdam	**1600**
22085 **10083**	A randomized phase III study of radiation doses and fractionation schedules for ductal carcinoma in situ (DCIS) of the breast. Study Coordinator: • Helen Westenberg, Arnhem 'S Radiotherapeutisch Instituut, Arnhem	**610**
26053 **22054**	Phase III trial on concurrent and adjuvant temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma. The CATNON intergroup trial. Study Coordinators: • Brigitta Baumert, Maastro Clinic - Maastricht Radiation Oncology, Maastricht • Martin J. van den Bent, Erasmus MC - Daniel den Hoed Cancer Center, Rotterdam	**748**
26062 **22061**	A randomized phase III study of Temozolomide and short-course radiation versus short-course radiation alone in the treatment of newly diagnosed glioblastoma multiforme in elderly patients Study Coordinator: • Alba Brandes, Ospedale Bellaria, Bologna	**560**
26081 **22086**	Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with Newly Diagnosed Anaplastic Oligodendroglioma or Anaplastic Mixed Glioma with Chromosomal Co-delections of 1p and 19q. Study Coordinators: • Frederic Dhermain, Institut Gustave Roussy, Villejuif • Martin J. van den Bent, Erasmus MC - Daniel den Hoed Cancer Center, Rotterdam • Wolfgang Wick, UniversitaetsKlinikum Heidelberg - Head Hospital, Heidelberg	**585**

26082 **22081**	Radiation therapy and concurrent plus adjuvant Temsirolimus (CCI-779) versus chemo-irradiation with temozolomide in newly diagnosed glioblastoma without methylation of the MGMT gene promoter - a randomized multicenter, open-label, Phase II study. Study Coordinator: ♦ Wolfgang Wick, UniversitaetsKlinikum Heidelberg - Head Hospital, Heidelberg	**108**
EORTC Soft Tissue and Bone Sarcoma Group		
62092 **22092**	A phase III randomized study of preoperative radiotherapy plus surgery versus surgery alone for patients with Retroperitoneal sarcomas (RPS) - STRASS Study Coordinator: ♦ Sylvie Bonvalot, Institut Gustave Roussy, Villejuif	**256**

Intergroup Trials Coordinated by the EORTC as of September 2012

Protocol	Title	Target Accrual
EORTC Brain Tumor Group		
26053	Phase III trial on concurrent and adjuvant temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma. The CATNON intergroup trial. Study Coordinators: • Brigitta Baumert, Maastro Clinic - Maastricht Radiation Oncology, Maastricht • Martin J. van den Bent, Erasmus MC - Daniel den Hoed Cancer Center, Rotterdam Other participating groups: • Cancer Trials Support Unit • Cooperative Trials Group for Neuro-Oncology • Medical Research Council Clinical Trial Unit • NCIC Clinical Trial Group • Radiation Therapy Oncology Group	**748**
EORTC Breast Cancer Group		
10085	Clinical and biological characterization of Male Breast Cancer : an international retrospective EORTC, BIG and NABCG intergroup study. Study Coordinator: • Fatima Cardoso, Champalimaud Cancer Center, Lisboa Other participating groups: • Borstkanker Onderzoeksgroup Nederland • Breast International Group • Schweizerisches Arbeitsgemeinschaft Klin. Krebsforschung • Swedish Association of Breast Oncologists	**1800**
EORTC Genito-Urinary Cancers Group		
30073	Randomized Phase III trial comparing immediate versus deferred nephrectomy in patients with synchronous metastatic renal cell carcinoma. Study Coordinators: • Axel Bex, The Netherlands Cancer Institute-Antoni Van Leeuwenhoekziekenhuis, Amsterdam • John B.A.G. Haanen, The Netherlands Cancer Institute-Antoni Van Leeuwenhoekziekenhuis, Amsterdam Other participating groups: • Canadian Urologic Oncology Group • German Association of Urologic Oncology • National Cancer Research Institute - Renal Cancer Group	**458**

EORTC Leukemia Group		
06031	Gemtuzumab ozogamicin (GO) monotherapy versus standard supportive care for previously untreated AML in elderly patients who are not eligible for intensive chemotherapy : a randomized phase II/III trial (AML-19) of the EORTC-LG and GIMEMA-ALWP. Study Coordinator: • Sergio Amadori, Azienda Ospedallera Universitaria - Policlinico Tor Vergata, Roma Other participating group: • Gruppo Italiano Malattie Ematologiche dell'Adulto	**260**
06061	Clofarabine in combination with a standard remissioninduction regimen (AraC and idarubicin) in patients 18-60 years old with previously untreated intermediate and bad risk acute myelogenous leukemia (AML) or high risk myelodysplasia (MDS) : a phase I-II study of the EORTC-LG and GIMEMA (AML-14A trial) Study Coordinators: • G. Meloni, Universita Degli Studi "la Sapienza", Roma • Dominik Selleslag, A.Z. St. Jan, Brugge • Roel Willemze, Leiden University Medical Centre, Leiden Other participating group: • Gruppo Italiano Malattie Ematologiche dell'Adulto	**120**

Intergroup Trials Not Coordinated by the EORTC as of September 2012

Protocol	Title	Target Accrual
EORTC Brain Tumor Group		
26062	A randomized phase III study of Temozolomide and short-course radiation versus short-course radiation alone in the treatment of newly diagnosed glioblastoma multiforme in elderly patients Study Coordinator: • Alba Brandes, Ospedale Bellaria, Bologna Coordinating Group: • NCIC Clinical Trial Group	**560**
26081	Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with Newly Diagnosed Anaplastic Oligodendroglioma or Anaplastic Mixed Glioma with Chromosomal Co-delections of 1p and 19q. Study Coordinators: • Frederic Dhermain, Institut Gustave Roussy, Villejuif • Martin J. van den Bent, Erasmus MC - Daniel den Hoed Cancer Center, Rotterdam • Wolfgang Wick, UniversitaetsKlinikum Heidelberg - Head Hospital, Heidelberg Coordinating Group: • North Central Cancer Treatment Group	**585**
EORTC Breast Cancer & Radiation Oncology Groups		
10112	A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer. Study Coordinator: • Fatima Cardoso, Champalimaud Cancer Center, Lisboa Coordinating Group: • Breast International Group	**3806**
22051	Selective Use of Postoperative Radiotherapy AftEr MastectOmy (SUPREMO) Study Coordinator: • Geertjan Van Tienhoven, Academisch Medisch Centrum - Universiteit van Amsterdam, Amsterdam Coordinating Group: • Scottish Cancer Trials Breast Group	**3700**

22085	A randomized phase III study of radiation doses and fractionation schedules for ductal carcinoma in situ (DCIS) of the breast. Study Coordinator: • Helen Westenberg, Arnhem 'S Radiotherapeutisch Instituut, Arnhem Coordinating Group: • Trans-Tasman Radiation Oncology Group Inc	**610**
EORTC Children's Leukemia Group		
58051	International collaborative treatment protocol for infants under one year with acute lymphoblastic or biphenotypic leukemia Study Coordinator: • Alice Ferster, Hopital Universitaire Des Enfants Reine Fabiola, Brussels Coordinating Group: • Operating Center for Research and Statistics	**445**
EORTC Genito-Urinary Cancers Group		
30072	A Phase III Randomised Double-blind Study Comparing Sorafenib With Placebo In Patients With Resected Primary Renal Cell Carcinoma at High or Intermediate Risk of Relapse Study Coordinators: • Steven Joniau, U.Z. Leuven - Campus Gasthuisberg, Leuven • Peter Mulders, Radboud University Nijmegen Medical Centre, Nijmegen Coordinating Group: • Medical Research Council Clinical Trial Unit	**1656**
EORTC Gynecological Cancer group		
55102	A phase III Trial of postoperative chemotherapy or no further treatment for patients with stage I-II medium or high risk endometrial cancer. Study Coordinators: • Frederic Amant, U.Z. Leuven - Campus Gasthuisberg, Leuven • Mansoor Raza Mirza, Rigshospitalet, Copenhagen Coordinating Group: • Danish Gynaecological Cancer Group	**678**
EORTC Leukemia Group		
06083	Clofarabine added to prephase and consolidation therapy in acute lymphoblastic leukemia in adults. A prospective randomized trial. Study Coordinator: • Jean-Pierre Marie, Hopital Saint Antoine AP-HP, Paris Coordinating Group: • Hemato-Oncologie Volwassenen Nederland	-

EORTC Lung Cancer Group		
08072	Concurrent once-daily versus twice-daily radiotherapy : A 2-arm randomised controlled trial of concurrent chemo-radiotherapy comparing twice-daily and once-daily radiotherapy schedules in patients with limited stage small cell lung cancer (SCLC) and good performance status (CONVERT). Study Coordinator: • Corinne Faivre-Finn, Christie NHS Foundation Trust, Manchester Coordinating Group: • Christie's Hospital	**532**

REPORTS FROM THE EORTC GROUPS AND TASK FORCES

For updated information on any EORTC Group or Task Force

or to request information about the schedule of a Group or Task Force meeting, plaase consult the EORTC website at http://www.eortc.org/research-groups where all details are posted.

Structure of the Group

Chair	**W. Wick, Heidelberg (DE)**
Secretary	**B.G. Baumert, Maastricht (NL)**
Treasurer	**M. Sanson, Paris (FR)**

Committee Chairs	
Pathology	M. Kros, Rotterdam (NL)
Translational Research	M. Hegi, Lausanne (CH)
Quality Assurance	P. Hau, Regensburg (DE)
Quality of Life	J. Reijneveld, Amsterdam (NL)

The primary aim of the Brain Tumor Group (BTG) is to conduct, develop, coordinate and stimulate clinical and translational research for the treatment of brain tumors and metastases. The BTG aims at a better understanding of the development of brain tumors and at the development of novel and more efficacious treatments to prolong the lives of brain tumor patients and to improve their quality of life.

Recent Achievements

The EORTC 22033/26033 phase III trial for the treatment of low grade gliomas has been completed. The data are maturing and translational research projects are in development.

The successful and rapid completion of the landmark study in newly diagnosed glioblastoma, the EORTC 26981/22981-NCIC CE.3 trial, proved the role of temozolomide (TMZ) early in the course of the disease concomitant with radiotherapy (RT). The results, published in the New England Journal of Medicine, have led to the rapid worldwide adoption of this treatment scheme as the new standard of care. In a large intergroup study (a collaboration of the North American Radiation Therapy Oncology Group [RTOG] and the EORTC) in which 1,173 patients were accrued in just over two years (16% from the EORTC) the role of dose-intensified TMZ in the maintenance phase was compared with the regular 5 out of 28 days regimen. The objective was to show superiority of dose-intensified TMZ over regular TMZ in the maintenance phase and to prospectively validate MGMT as a predictive marker for choosing alkylating agent chemotherapy, a first step toward individualized treatments, and at testing strategies to overcome resistance mediated by this repair protein. Although negative for the primary endpoint, the prognostic significance of MGMT methylation in glioblastoma treated by standard TMZ/RT or an intensified regimen was confirmed. However, in absence of an arm without TMZ, it could not validate the predictive value of MGMT (J Clin Oncol 2011;29(15):suppl 2006). This study marked the first successful collaboration between a US Cooperative Group and the BTG. It has set the stage for the now almost standard collaboration of North-American Cooperative Groups and EORTC for several other subtypes of glioma, allowing the investigation, in a randomized fashion, of those burning questions concerning the management of primary brain tumors. Furthermore, all these trials now include mandatory submission and review of tumor material and characterization with modern molecular methods.

The joint EORTC Radiation Oncology Group (ROG) /BTG study on the treatment of brain metastases has been completed with 359 patients accrued. Results were presented at ASCO 2009. After radiosurgery or surgery of one to three brain metastases, adjuvant whole brain radiation therapy (WBRT) reduces the frequency of intracranial relapses and neurologic deaths but fails to prolong the time period of functional independence and overall survival time.

In a recent trial update, EORTC 26951 trial investigating adjuvant procarbazine/ lomustine/ vincristine (PCV) chemotherapy after RT in the more chemosensitive anaplastic oligodendroglioma (AOD) and oligoastrocytoma (AOA) showed a statistically significant prolongation in progression-free and overall survival by the addition of PCV in the group of tumors, in particular those with 1p/19q co-deletions. We concluded that the 1p/19q co-deletion is predictive regarding the administration of alkylating chemotherapy in this disease (J Clin Oncol 2012;30(18)suppl 2). The findings of the study are completely in agreement with a similar North-American study led by Dr Cairncross. Of note, these studies showed these results 17 years after study initiation, showing the importance of long term follow up. Only academic groups are able to deliver this kind of ongoing commitment, emphasizing again the role of academic research in the definition of standard of care for cancer patients.

Analysis of the health related quality of life (HRQOL) data from the EORTC 26981 and 26951 trials showed that the addition of chemotherapy has only a limited and transient negative impact on HRQOL during and shortly following treatment. Not unexpectedly and although not compared in one trial nor one entity, TMZ had a less negative impact than PCV. Baseline HRQOL data demonstrated no additional prognostic significance compared to clinical data. Future studies should include longitudinal HRQOL measurements especially following radiological recurrence. From a patient perspective, time to clinical deterioration may be a more relevant endpoint than time to progression if this progression is still asymptomatic. To meet this requirement, the validation of novel and more clinical endpoints is required.

Novel drugs have been tested in a series of phase I and phase II studies in glioblastoma and anaplastic glioma. Recent agents under investigation are lonafarnib, enzastaurin, and sagopilone. Erlotinib, an epidermal growth factor (EGFR) tyrosine kinase inhibitor [TKI], has been evaluated in a randomized phase II trial. In contrast to previous reports from the US of promising activity of this drug as a single agent in recurrent glioma, our trial did not show significant activity in recurrent glioblastoma; the finding of a molecular profile associated with response to EGFR TKIs in US trials could not be confirmed in this trial. Since then, several other US and European projects on similar agents also failed to produce meaningful results. A phase I study of combined chemo-irradiation (TMZ/RT) adding the VEGFR TKI PTK 787 demonstrated feasibility and safety. Unfortunately, the drug manufacturer decided to discontinue development of this agent and the planned randomized phase II study was not started.

Project/strategies for the coming years

Playing a major role in intergroup set ups and following the closed RTOG trial, the BTG is leading the CATNON trial which addresses the role of concurrent and adjuvant TMZ in non-1p/19q deleted anaplastic glioma. This study is performed in cooperation with RTOG, NCI Canada, NOA Germany, COGNO Australia, and MRC in the UK.

A NCCTG led Phase III Intergroup Study of RT versus TMZ alone *versus* RT with concomitant and adjuvant TMZ for patients with newly diagnosed AOD or anaplastic mixed glioma with chromosomal co-deletions of 1p and 19q (CODEL trial) is being activated. The trial design is currently under review following the recent results of long term follow-up of the EORTC 26951 and RTOG 9402 studies.

The BTG is pursuing the development of neurocognitive testing in active trials such as the CATNON and the CODEL.

In a back to back program with pharmaceutical industry in the newly diagnosed setting of glioblastoma patients, we are investigating the integrin inhibitor cilengitide in combination with standard TMZ chemoradiation followed by adjuvant TMZ chemotherapy. This trial was being conducted in a close and novel collaboration with the manufacturer, Merck-Serono, as an international effort led jointly by the EORTC and the Sponsor and had finished accrual already early 2011.

For patients with glioblastoma without MGMT promoter methylation, the currently recruiting randomized phase II EORTC 26082 trial explores the activity of temsirolimus (CCI-779) an inhibitor of the mammalian target of rapamycin (mTOR).

Another innovative approach is another example of the collaboration between EORTC and industry. This project on rindopepimut will investigate immunotherapy for the treatment of glioblastoma with EGFRvIII mutation, and is currently in the process of activation (EORTC 26112-22115). Rindopepimut is used as an immunotherapy designed to generate an immune response against EGFRvIII. In the setting of resected primary glioblastoma, this immune response is intended to target tumor cells that remain after surgery and radiochemotherapy.

The study on RT hypofractionation with or without TMZ in elderly glioblastoma patients (co-project leaded by NCIC) is recruiting (EORTC 26062) well, with a major collaboration of European sites.

In the recurrent setting, two trials with bevacizumab are currently active. 26091 (TAVAREC) is investigating whether recurrent contrast-enhancing low-grade or anaplastic gliomas may benefit from the addition of bevacizumab to TMZ. In a study on first recurrences of glioblastomas after standard-of-care the optimal sequence of lomustine and bevacizumab is tested in a four-armed phase II approach. Both trials are accompanied by substantial imaging and molecular translational research projects. The first is possible by the use of a uniform imaging protocol and the central evaluation of all imaging data. The latter aims at defining a biomarker aiding the decision who and when antiangiogenic treatment with bevacizumab should be applied at recurrence.

The adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma study in cooperation with the EORTC Radiation Oncology Group (ROG) is continuing (EORTC 22042 – 26042).

Translational Research

A substantial inter-observer variation between pathologists on the diagnosis of Grade III gliomas has been demonstrated in the EORTC 26951 trial, and many of the tumors included in this study were observed to have molecular abnormalities one expects to occur in glioblastoma. The virtual microscopy project for histopathological panel review of tumor slides collected in the EORTC 26951 and 26882 (Anaplastic Astrocytoma) trials is ongoing. It will allow reviewing the WHO criteria for gliomas.

In the EORTC 26981 glioblastoma trial, gene expression signatures associated with treatment resistance have been identified as independent prognostic factors in glioblastoma patients treated with TMZ/RT and identify patients who may benefit from other additional treatment strategies.

Based on the molecular and clinical data collected in the EORTC 26951 trial, several translational research projects have been conducted. Molecular characterization demonstrated a different natural history in a subgroup of oligodendroglioma with 1p/19q deletion (recently identified as a translocation). These projects allowed the identification of IDH1 and IDH2 mutations and MGMT promoter methylation as prognostic factors in AOD and AOA but not as predictive factor of response to chemotherapy, and also allowed the characterization of the role of different biomarkers (EGFR amplification, 1p and 19q loss, loss of chromosome 10q or 10, trisomy of chromosome 7) for improving the diagnosis of gliomas. Except 1p/19q for PCV, it is not yet clear if and which biomarker can be used for treatment decision. In particular the potential role of CpG island hypermethylation is interesting.

In the low-grade glioma EORTC 22033/26033 trial, an ambitious program is in development. The main goals are the identification of new therapeutic targets, the identification and the development of diagnostic, prognostic and predictive biomarkers, the retro-translation into in vitro and in vivo models (human xenografts, genetically engineered mice) mimicking the disease for preclinical studies, and the design of new treatment approaches for low-grade gliomas.

A large Translational Research program is under discussion on the material collected in the CATNON trial. It aims to study and confirm the role of several molecular markers such as 1p/19q, IDH1/2 mutation, and MGMT promoter methylation. In addition, it will explore tumor genomic profiles through gene expression, copy number, micro RNA, and epigenetic analyses. This translational research program may help biomarker development, possibly identifying new markers, and lead to new therapeutic strategies such as targeting IDH.

Imaging

Increasing demand on the imaging and recent discussions on phenomena such as pseudoprogression (after RT and TMZ) and pseudoresponse (a restoration of the integrity of the blood-brain-barrier by antiangiogenic compounds) has led to the implementation of neuroradiology/imaging as a core committee of the BTG. This is in conjunction with the Imaging Group of the EORTC. First major steps are the design and set-up of a uniform imaging protocol for all future brain tumor trials. Further, a perfusion MRI protocol will be implemented into the transatlantic CATNON trial.

Quality Assurance

In collaboration with the ROG Quality Assurance (QA) Team, a special Facility Questionnaire was developed for use by non-EORTC participants in the CENTRIC study (Cilengitide). Transversal Quality Assurance in Radiotherapy (QART) programs are on-going for all BTG studies in cooperation with the ROG.

The activities of the QA Committee have been extended with the initiation of the intergroup RTOG-EORTC study on glioblastoma. New members of the BTG wishing to participate in this study

were site visited prior to the start of the study. Currently, for all BTG studies in which RT is part of the treatment, the Facility Questionnaire developed by the Radiation Oncology Group is used to evaluate the RT installation of all participating centers. Furthermore, minimum RT requirements are being defined for participation in BTG studies including dummy runs, all of which are overseen by the ROG with which the BTG closely collaborates.

The BTG has revitalized its own QA activities which will focus on quality criteria for medical oncology and is involved in document validation such as protocol.

Collaboration with other groups

Within the EORTC, the BTG collaborates for most trials with the ROG, specifically the ROG QA Team. Ongoing successful collaborations exist also with the EORTC Quality of Life Group aimed at developing improved tools allowing evaluation of the burden of brain cancer related symptoms, effect of treatment of symptoms but also toxicity, and finally quality of life adjusted outcome measurements. Recently, collaboration with the EORTC Imaging group on the use of central MRI upload and reading has been developed.

Outside the EORTC, the BTG collaborates with the NCI-C (Canada), Cancer UK (Medical Research Council; MRC), the RTOG, and HUB (a brain tumor collaboration of ECOG, SWOG and NCCTG) as well as the Neuro-Oncology Group of the NOA and Australia based groups (TROG and COGNO).

www.eortc.org/research-groups/brain-tumor-group

Structure of the Group

Chair	**D. Cameron, Edinburgh (UK)**
Secretary	**F. Cardoso, Lisbon (PT)**
Treasurer	**E. Rutgers, Amsterdam (NL)**

Steering Committee Members

J. Bogaerts, Brussels (BE)
H. Bonnefoi, Bordeaux (FR)
E. Brain, Paris (FR)
D. Cameron, Edinburgh (UK)
F. Cardoso, Lisbon (PT)
S. Delaloge, Villejuif (FR)
M. Ignatiadis, Brussels (BE)
J. Jassem, Gdansk (PL)
K. Engelen, Brussels (BE)
S. Litière, Brussels (BE)
S. Marréaud, Brussels (BE)
C. Messina, Brussels (BE)
E. Rutgers, Amsterdam (NL)
G. Van Tienhoven, Amsterdam (NL)
H. Westenberg, Arnhem (NL)

The EORTC Breast Cancer Group (BCG) is a multidisciplinary group involving surgeons, medical oncologists, pathologists, radiation oncologists, basic scientists and clinical research fellows. The main goal of the BCG is to carry out high quality international clinical trials. Over the last three years, the BCG has recruited a total of over 4,000 patients for participation in clinical trials at an average of 1,340 patients per year.

Recent Achievements

EORTC trial 10994 p53 is an intergroup translational research trial. It prospectively randomized 1,856 patients to test the hypothesis that a neo-adjuvant taxane regimen confers a greater advantage over an anthracycline regimen in p53 mutated tumors than in p53 wild type tumors. The final results of this trial were presented at ASCO 2010 and published in Lancet Oncology in 2011. At a median follow up of 57 months, p53 did not demonstrate to be a predictive factor of response or resistance to taxanes. However, the prognostic value of p53 in early breast cancer has been confirmed. Further analyses are ongoing.

Projects/Strategies for the coming years

EORTC trial 10041 BIG 3-04 MINDACT recruited more than 6,600 patients in 111 institutions across nine countries from February 2007 to July 2011. MINDACT is an EORTC sponsored multi-center, prospective, phase III trial whose participants are early stage breast cancer patients who are

either node negative or have one to three positive lymph nodes. It compares the 70-gene prognostic signature (Mammaprint), a genomic test developed with micro-array technology, to traditional clinical-pathological methods for assessing the risk of breast cancer recurrence in women with early breast cancer. It is hypothesized that using the genomic test in addition to traditional methods will result in a more accurate risk assessment so that in the future 10 to 20 percent of patients could safely avoid adjuvant chemotherapy and its potential side effects.

The MINDACT trial reached its first milestone in November 2008 by accruing the first 800 patients for the pilot phase. The preliminary results of this phase, presented at EBCC 2010, demonstrated that the trial was logistically feasible, that the compliance rate of both physicians and patients is high, and that the overall process provides data and biological materials of good quality.

The trial has an associated process to review proposals for additional translational research. Many projects are already ongoing. Baseline and chemotherapy compliance data are in final cleaning in order to be able to fully report the prognosis of the patients enrolled, as well as the compliance to the chemotherapy decision.

EORTC trial 10981-22023 AMAROS (After Mapping of the Axilla: Radiotherapy Or Surgery) is a phase III study comparing a complete axillary lymph node dissection with radiotherapy to the axilla in sentinel node positive patients. Sentinel node negative patients are given no further axillary treatment but are still being followed for the end-points of the study. Patients included have operable invasive breast cancer greater than 5 millimeters and less than 5 centimeters without clinically compromised regional lymph nodes. The main objective of the trial is to provide equivalent local/regional control for patients with proven axillary lymph node metastases, as detected by sentinel node biopsy, with reduced morbidity by treating with axillary radiotherapy instead of axillary lymph node dissection. The study completed accrual in April 2010 with 4,828 patients included. Follow-up prior to primary analysis is currently ongoing.

The currently recruiting **EORTC 10054 Lapatax** phase I/II trial was designed to compare the use of Lapatinib, Herceptin and a combination of the two when given in conjunction with Docetaxel during FEC-D neoadjuvant chemotherapy for large operable and locally advanced breast cancer. The phase I part of the study determined the recommended doses of Lapatinib and Docetaxel. The dose determination study has confirmed that with primary prophylactic G-CSF, docetaxel 100 mg/m2 can be safely and effectively given with lapatinib 1,250 mg daily on a continuous basis. Prior to treatment, frozen tumor and blood samples were taken to better define which tumors were particularly sensitive to either trastuzumab and/or lapatinib. The phase II part of the study was opened in October 2010. It will enroll 100 patients from European centers into a two-arm randomized trial whose primary endpoint is pathological complete response. Today there are fourteen open centers in five countries participating in the trial. As of 06 September 2012, 87 (70 percent) patients were enrolled in the Phase II part. All patients will receive FEC- D before primary surgery: three cycles of docetaxel plus either trastuzumab (conventional weekly schedule) or the combination of trastuzumab and lapatinib followed by three cycles of FEC (without anti-HER2 therapy).

The currently recruiting **EORTC 22051-10052 SUPREMO** (Selective use of postoperative radiotherapy after mastectomy) intergroup trial was designed to determine the effect of ipsilateral chest wall irradiation following mastectomy and axillary clearance for women with operable breast cancer at 'intermediate risk' of loco-regional recurrence. The primary endpoint is overall survival. The number of patients required is 1,600, with accrual currently at approximately 810 patients. Accrual to date has been slower than anticipated, so an amendment is planned to broaden the eligibility

criteria. This will extend enrolment to patients with clinical stage T3N0 or T1-2 N0-1 or T1-2 N0 with additional risk factors, patients who have received neo-adjuvant systemic therapy, patients carrying BRCA 1 or 2 gene mutations, patients with histologically positive internal mammary sentinel nodes, and patients with pN1 in whom fewer than ten lymph nodes were obtained on an axillary clearance. This study prospectively studies the cardiac toxicity of the radiotherapy and collects tumor samples in order to be able to study biological characteristics of those tumors that do and do not recur, both with and without radiotherapy.

The **EORTC 10085** male breast project is an intergroup EORTC led project which consists of three parts: 1) a retrospective joint analysis of clinical and centrally reviewed pathological data with the aim of improving our knowledge about the biology of male BC; 2) a prospective international registry and 3) an endocrine therapy clinical trial if deemed feasible.

The first part of the program is fully running with the following countries participating: the United States of America, Belgium, the United Kingdom, Poland, The Netherlands (BOOG), Ireland (ICORG), Spain, Switzerland (SAKK) and Sweden (SABO), making this a truly international effort. Until recently, about 450 patients have been registered with corresponding tumor blocks and this number will now rapidly increase. The collection of FFPE samples in Europe and pathological review by the European central lab has started in the second half of 2011 and it is about to start in the US. It is expected to complete the collection of all tumor blocks by the end of 2012, and then start the translational research analyses by the first quarter of 2013 to allow presentation of results at an important breast cancer conference in 2013. The retrospective part will be soon amended to the prospective part that will start from early 2013.

www.eortc.org/research-groups/breast-cancer-group

Structure of the Task Force

Chair	**H. Wildiers, Leuven (BE)**
Secretary	**E. Brain, Saint-Cloud (FR)**
Treasurer	**U. Wedding, Jena (DE)**
Young oncologists	L. Dal Lago, Brussels (BE) A. Luciani, Milano (IT)

Recent achievements

The EORTC Cancer in the Elderly Task Force (ETF) focuses on developing clinical trials in collaboration with the EORTC disease oriented groups and on strategic aspects in the field of geriatric oncology.

The ETF established a standardized Elderly Minimal Dataset (MinDS) for the purpose of harmonizing the collection of data relevant to the elderly and to enable future cross study/practice comparisons (Ann Oncol 2011;22(8):1922-1926). It was emphasized that the dataset need not be restrictive or comprehensive but rather should form the backbone upon which individual investigators could add assessment tools pertinent to the particular study or specific local interests. It is anticipated that this dataset will evolve over time with addition, removal, or refinement of tools as more data become available. A key aspect of the dataset is that it includes instructions for completion of the tools, as there are some controversies in this area. The MinDS includes four elements: Charlson Co-morbidity Index (CCI), G8 Geriatric Assessment Screening Tool, Instrumental Activities of Daily Living (IADL, and Social Situation.

The ETF has collaborated with the EORTC Quality of Life Group in developing an elderly specific tool, the QLQ-ELD15 scale (Eur J Cancer 2010;46(12):2242-2252). This quality of life scale will also be integrated in future elderly studies.

The ETF is also active in developing specific methodology for clinical trials in the elderly. Two papers regarding standardization and unmet need of clinical trials in elderly population were written in 2010:

- EORTC Elderly Task Force Position Paper: Approach to the Older Cancer Patient (Eur J Cancer 2010;46(6):1019-1025).
- EORTC workshop on clinical trial methodology in older individuals (Ann Oncol 2011;22(8):1922-1926). This paper is a summary of a workshop (under the auspices of EORTC) on clinical trial methodology in older cancer patients that was held at EORTC Headquarters in December 2009. Consensus was reached on which elements the MinDS tool should include.

In November 2011, a second workshop was held in Paris on clinical trial methodology in a joint collaboration between the EORTC, the International Society of Geriatric Oncology (SIOG), and the Cancer and Leukemia Group B (CALGB). The following items were discussed at this meeting:

1. **Areas of highest research priority in geriatric oncology:** it was decided that new comprehensive geriatric assessment (CGA) tools are not needed, rather, we should fine-tune existing ones, e.g. for predictive and prognostic value. It was acknowledged that there is a validated tool, the

MAX2 index, which allows comparison of differential individual toxicity in patients/studies using different chemotherapy regimens. There is a need for pharmacokinetics studies and a global approach to obtain pharmacokinetic data in the elderly for drug approval.

2. **How to define not fitness for clinical trials:** the definition of frailty might differ significantly according to the setting and purpose: e.g. fitness for adjuvant chemotherapy might be different than for metastatic setting.
3. **Clinical endpoints and trial designs in elderly:** it was decided to form a working group to draft a publication on various potential endpoints relevant for elderly patients. Reimbursement organizations only reimburse expensive drugs for older patients if a minimum amount of geriatric data is provided, so this can offer a way of obtaining more data in the elderly. Besides the topics discussed, long-term outcomes/toxicity should also be included as potential endpoints. Endpoints should probably be much different for adjuvant therapy (overall survival or adapted survival definition) compared to metastatic setting (toxicity, quality of life).
4. **Cancer registry studies in elderly:** it was uniformly approved that there is a huge need for observational cohort studies to obtain more information on the population with the most needs, i.e., frail patients. Randomized trials are particularly difficult in frail patients, and there is a very great danger of selection bias and exclusion of the frailest patients. Cohort studies provide a view of the entire study population regardless of whether they are entered in a randomized study. This will lead to a much better view on the global population than would randomized trials.
5. **Geriatric intervention studies:** several trials are ongoing, but the 'control' arms, and definitions of 'intervention', can be very challenging.
6. **Minimum geriatric data collection in clinical trials:** EMA is working on the integration of some frailty tools in the approval process of new drugs.

The ETF generated a template letter for reviewing EORTC study proposals from other EORTC groups through the Protocol Review Committee; we want to provide a global strategy across tumor types and in different settings. Suggestions include the necessity to mention up front in protocols that an age related sub-analysis will be performed (e.g. with age cutoff at 70 years). This sub-analysis should focus both on efficacy and toxicity, since data show that toxicity increases significantly in older people, and that the 'small/moderate' benefit in progression free survival could be counterbalanced by toxicity (while more benefit might be present in younger patients). Secondly, we emphasize the need to have a sufficient number of elderly patients in large clinical trials. It is important that the study population represents the real population. This could be done for instance by requiring a minimum fixed percentage of patients over 70 years of age (avoiding over selection younger patients in clinical trials). The percentage could differ by setting. Thirdly, in parallel with other studies, and according to international guidelines and EORTC proposal, we would recommend a "minimum geriatric assessment" in all patients above 70 years of age (cfr supra: minimum dataset).

Projects/Strategies for the coming years

In collaboration with the EORTC disease oriented groups, two clinical trials were developed and will start recruitment in the last quarter of 2012.

- EORTC trial 40085-75083 in colorectal cancer (PI M. Peeters and Ulrich Wedding): A phase III randomized trial of 5-FU+ cetuximab versus 5-FU alone in patients with metastatic colorectal

cancer and wild type kras status. The main objective is to determine if elderly, especially 'unfit' elderly, derive benefit in terms of progression free survival from a regimen consisting of less toxic chemotherapy plus a biological agent with limited toxicity. Accrual of 228 patients (136 kras wild type) is required.

- EORTC trial 75091-10095 in breast cancer (PI H. Wildiers): A phase II randomized trial of pertuzumab + trastuzumab (PH) versus PH + metronomic cyclophosphamide as first line chemotherapy in elderly patients with metastatic Her2 positive breast cancer. In case of progression, T-DM1 will be offered to all patients. The objective is to assess the efficacy (progression free survival) and the toxicity of PH with or without metronomic cyclophosphamide in a general elderly population. Accrual of 80 patients is planned.

Several other trial proposals are in different stages of development, such as a randomized trial of sequential versus concomitant chemoradiotherapy in non-small cell lung cancer (NSCLC); Nab-paclitaxel in lung cancer; adjuvant chemotherapy in luminal B breast cancer (coordinated by Unicancer); specific trials for acute myeloid leukemia in older patients.

Translational research

The ETF is initiating a biobank for peripheral blood to study potential ageing biomarkers. Given the paucity of large clinical trials currently running in the elderly population, it is of crucial importance to create a European biobank of biological samples which can be used for future research projects. Initially this will involve the collection and storage of blood samples. Ageing markers of interest are: telomere length, expression of p16 in peripheral leukocytes, circulating Il-6, TNF-α and IL-10, single nucleotide polymorphisms (SNPs) in several age related genes such as apoE and FOXO3A genes, age related miRNA expression, and age related gene expression profiling.

A template protocol for biobanking in elderly trials has been established that can be built into different protocols.

Collaboration with other groups

Within EORTC

ETF aims to develop elderly specific trials for those patients who are not candidates for standard treatment. This will be accomplished in collaboration with the EORTC disease orientated groups. Collaborations with the EORTC Breast Cancer, Lung Cancer, Leukemia, Gastrointestinal Tract Cancer, and Brain Tumor Groups have been established. Collaboration with the Quality of Life Group continues in the validation of an elderly specific quality of life questionnaire.

Outside the EORTC

For the above mentioned trial on metastatic colorectal cancer, collaboration with the AIO (Arbeitsgemeinschaft Internistische Onkologie) of the German Cancer Society has been established.

For geriatric assessment, close collaboration is ongoing with the French geriatric cancer units who developed the G8 screening tool.

National groups in which several ETF members are actively involved will also be contacted for support of clinical trials.

Hans Wildiers, the current chairman, has been appointed in 2010 as EORTC representative in the geriatric expert group of the EMA. This expert group is currently working on a uniform frailty tool that can/should be integrated for older individuals in all drug clinical trials in the future.

www.eortc.org/research-groups/cancer-elderly-task-force

Structure of the Group

Chair	**Y. Benoit, Ghent (BE)**
Secretary	**G. Plat, Toulouse (FR)**
Treasurer	**B. De Moerloose, Ghent (BE)**
Vice-Chair	Y. Bertrand, Lyon (FR)
Other Board Members	H. Cavé, Paris (FR) V. Costa, Porto (PT) N. Dastugue, Toulouse (FR) A. Ferster, Brussels (BE) F. Mazingue, Lille (FR) A. Uyttebroeck, Leuven (BE)
Young Oncologists / Scientists	V. Costa, Porto (PT) C. Piette, Brussels (BE) T. Lammens, Ghent (BE)

EORTC Children's Leukemia Group (CLG) meetings are held twice a year. The CLG comprises 24 pediatric centers in Belgium, France, and Portugal.

Introduction to the group including significant achievements

While the main activity of the CLG was concentrated on the field of acute lymphoblastic leukemia (ALL), acute myeloid leukemia and lymphoblastic lymphoma's were also in the spectrum of clinical research. Fine tuning of treatment elements for ALL in a backbone of the BFM design was done very successfully during the following decades. The CLG has many achievements, and the major ones include: EORTC trial 58832 which showed the superfluity of the prophylactic Central Nervous System (CNS) radiotherapy in ALL patients when adequate systemic and CNS directed chemotherapy is ascertained, EORTC trial 58881 which demonstrated that the assessment of minimal residual disease (MRD) at completion of induction in ALL is a key step in the process of categorizing and allocating patients into different risk groups and that MRD is a powerful and independent prognostic factor. This same trial showed the clear difference in efficacy of different asparaginases resulting in an optimization of the use these drugs and a revival of interest in asparaginases for treating ALL.

Future Strategies

The CLG plans to focus mainly on innovative biologically targeted treatment approaches. Optimal use of the antileukemic agents, molecular genetic analyses of leukemic cells, pharmacodynamic studies of drugs, pharmacogenetic studies of the host's drug-metabolizing enzymes, drug transporters, and drug targets are providing a rational and scientific basis for further improvement of treatment efficacy as well as for the reduction of complications. Also early treatment response, as defined by the measurement of MRD, which reflects both the drug responsiveness of leukemic cells and host

pharmacodynamics/pharmaco-genomics, is a reliable prognostic indicator for gauging the intensity of treatment.

Another important focus of CLG activities is translational research (TR), where better understanding of the biology of leukemia is needed and will help to identify refined prognostic and predictive factors and develop novel molecular and cellular therapeutics. This can certainly be better accomplished by centralizing the collection of clinical data in parallel with sampling, processing and storing biological samples according to well-defined standard operating procedures (biobanking). A centralized procedure will allow the storage of a large number of quality-controlled biological samples and the collection of relevant associated clinical data. A standardized and large collection of biological and clinical data will also give the possibility to develop well designed TR projects, even for small ALL subgroups, whose results would form the basis for the design of new clinical and biological research projects. In this context, the CLG successfully started a prospective biobanking study (EORTC trial 58081) with associated important TR projects.

In Europe, most cooperative groups for the treatment of acute leukemia in children are organized on a national basis. The CLG, which currently includes French, Belgian and Portuguese centers, is open to pediatric hematology-oncology centers or groups from all countries, and it also favors increased collaborations with other groups. Since the EU-directives have changed the world of clinical research trials in Europe, the role of the CLG in coordinating international studies can become more important due to the knowledge and experience EORTC Headquarters has in this domain. The CLG was one of the founding members of the international acute lymphoblastic leukemia I-BFM-SG (International BFM Study Group) and of the Ponte di Legno Group. These collaborations have led to substantial progress in leukemia research. By pooling data from all major study groups, it has been possible to improve the understanding of the biology and heterogeneity of subtypes of the disease and to acquire insight into their optimal therapy.

As cure rates in leukemia and lymphoma improve, more children experience late toxicity from their therapy, sometimes leading to late excess mortality. The increasing number of survivors has prompted studies of the long-term health consequences of treatments for childhood cancer. It is clear that damage to the organ systems of children caused by chemotherapy and radiation therapy may not become clinically evident for many years.

The most common late toxic effects are cardiotoxicity, growth retardation, obesity, endocrine disorders, fertility impairment, central nervous system effects and secondary neoplasms. Assessment of the long-term survival of children cured of cancer must consider also their social outcome. Age at diagnosis, sex, current age, socio-economic status, and life transitions may affect social outcome of childhood cancer survivors. The treatment type or intensity may also affect psychosocial functions.

Based on its vast experience, the CLG had the opportunity to analyze a large series of childhood ALL and Non-Hodgkin's Lymphoma (NHL) survivors with long term follow up and treated according to well defined protocols. A better understanding of the long-term follow up and the late adverse events is indeed essential in view of the improvements of cure rates, would be useful in order to set up a specific and standardized long term follow up for patients treated for childhood ALL and NHL in EORTC studies, and would help to further adapt therapy in order to avoid overtreatment of low risk patients and therefore reduce as much as possible the occurrence of late effects in this population.

www.eortc.org/research-groups/childrens-leukemia-group

Structure of the Task Force

Chair	**R. Stadler, Minden (DE)**
Secretary	**P. Quaglino, Turin (IT)**
Treasurer	**M. Vermeer, Leiden (NL)**
Young Oncologists	M. Karpova, Zurich (CH) M. Beyer, Berlin (DE)

Steering Committee

The Cutaneous Lymphoma Task Force (CLTF) Steering Committee is comprised of the Task Force's Executive Committee plus M. Bagot, Paris, R. Knobler, Vienna, S. Whittaker, London, and P. L. Ortiz-Romero, Madrid. The CLTF Steering Committee defines the CLTF scientific strategy.

Recent Achievements

Closed Trials

- **EORTC trial 21011**: A randomized, open-label phase III trial to evaluate the safety and efficacy of targretin capsules combined with PUVA (Psoralens, P, in combination with ultraviolet light, UVA) compared to PUVA treatment alone in patients with stage IB-IIA cutaneous T-cell lymphoma (CTCL). This study was activated in October 2003 and was closed due to poor accrual in May 2010. 94/145 patients were included. Final Analysis was conducted in October 2011, and the results have been published (Brit J Dermatology 2012:167(3);678-687.)
- **EORTC trial 21012**: Phase II clinical trial with caelyx mono-chemotherapy in patients with advanced Mycosis Fungoides stage IIb, IVa and IVb with or without previous chemotherapy. A manuscript describing the results of this study has been accepted for publication in Journal of Clinical Oncology.

Ongoing trials

- **EORTC trial 21081**: A phase III study of lenalidomide maintenance after debulking therapy in patients with advanced CTCL. This trial was opened for recruitment in 2010.

There is strong evidence associating CTCL with aberrant production of Th2 cytokines and chemokines, especially in advanced disease. A translational research component of EORTC trial 21081, therefore, is to:

- determine whether treatment with lenalidomide modulates the levels of circulating cytokines and chemokines;
- determine whether treatment with lenalidomide modulates cellular immune function using quantitative and qualitative assays;
- determine whether these changes correlate with clinical outcome and clinical response as defined previously (complete and partial response versus stable or progressive disease) and other clincopathological parameters.

Projects/Strategies for the coming years

Clinical Trials

A CLTF clinical trial platform has been discussed and built in order to improve the treatment of patients with advanced CTCL. The CTCL platform currently includes two successive trials. The ongoing EORTC 21081trial is the first trial in this platform, and EORTC trial 21082, progression free survival comparison between suberoylanilide hydroxamic acid (SAHA, Vorinostat), and the combination of SAHA and bortezomib (Velcade) in refractory or recurrent advanced CTCL, is the second trial in the CTCL platform. The protocol for this trial has been finalized, and the first site activation is expected in Q1 2013.

A third trial in the CTCL platform, an evaluation of reduced intensity allo-stem cell transplantation in a series of patients with advanced refractory CTCL, is under discussion.

Collaboration with other groups

The CLTF collaborated with the International Society for Cutaneous Lymphomas and the United States Cutaneous Lymphoma Consortium in producing a consensus statement on clinical endpoints and response criteria in mycosis fungoides and Sézary Syndrome (J Clin Oncology 2011;29(18):2598-2607).

www.eortc.org/research-groups/cutaneous-lymphoma-task-force

Structure of the Group

Chair	**M. Schlumberger, Villejuif (FR)**
Secretary	**L. Licitra, Milano (IT)**
Treasurer	**L. Bastholt, Odense (DK)**

The main objectives of the EORTC Endocrine Tumor Task Force (EnTF) are to:

- run potentially practice changing clinical trials;
- define and implement a global translational research strategy to better identify new targets and predictive and prognostic factors which could identify sub-populations likely to benefit;
- cultivate a network of experts that will be able to perform clinical trials in rare endocrine tumors.

The EnTF benefits from interactions with other EORTC groups and the support of EORTC structures such as the Translational Research Advisory Committee, the New Drug Advisory Committee, the Imaging Platform, and EORTC Headquarters expertise (e.g. the Quality of Life Department, Early Project Optimization Department, Regulatory Affairs, Pharmacovigilance, biostatistics, and methodology). To achieve these objectives, the EnTF will create subcommittees and other administrative structures as needed.

Recent Achievements

Second line treatment options for patients with differentiated thyroid cancer (DTC) and medullary thyroid cancer (MTC) who have progressed on first line treatment are limited, and no standard of care exists while patients are still in good prognosis. Inhibition of VEGFR has proven to be a successful therapeutic strategy in thyroid cancer in which drugs such as bevacizumab, sorafenib, sunitinib, axitinib and motesanib have shown activity as single agents.

Vargatf (BIBF1120) is a triple angiogenesis inhibitor which inhibits receptors of vascular endothelial growth factor (VEGF), fibroblast growth factor (FGF), and platelet derived growth factor (PDGF). By targeting these three major angiogenesis signaling pathways, it is believed that further tumor growth and related tumor escape mechanisms can be prevented. Based on this information, a phase II study exploring the safety and efficacy of BIBF1120 as second line therapy for patients with either DTC or MTC progressing after first line therapy has been designed and is currently in development.

Strategy for the coming years

It was decided to initially focus on thyroid and adrenal glands, and key investigators from both of these disease areas are equally represented in the EnTF.

The EnTF strategy will focus on:

1. **Pan European studies**
   In order to be successful in these rare tumors, sufficient numbers of patients need to be enrolled into clinical trials. Many trials in these diseases have been discontinued due to poor enrollment.

The goal of the EORTC is to simplify, streamline and harmonize clinical trials in these diseases across Europe.

2. **Translational research**
   Translational research is important for better identification of predictive and prognostic factors as well as to identify patient populations most likely to benefit. The EORTC, with its strong focus and background in translational research and bio banking, will be able to foster and maintain robust translational research projects.

3. **Collaboration with national and international groups**
   In line with its long term strategy, the EORTC has developed an excellent track record of transcontinental intergroup collaboration. The expertise of EORTC Headquarters regarding legal and regulatory issues is highly respected, and this is of significant value in terms of conducting efficient international collaborations.

The EnTF has already established links with the EORTC Imaging Group, and preliminary discussions are taking place with the European Network for the Study of Adrenal Tumors (ENSAT), a European academic group addressing adrenal gland tumors for complementary synergy.

www.eortc.org/research-groups/endocrine-task-force

Structure of the Group

Chair	**A. Roth, Geneva (CH)**
Secretary	**M. Ducreux, Villejuif (FR)**
Treasurer	**T. Ruers, Amsterdam (NL)**

The EORTC Gastrointestinal Tract Cancer Group (GI Group) strategic plan focuses on the following priorities:

- Translation research (TR) in collaboration with the EORTC Pathobiology and Pharmacology and Molecular Mechanisms Groups;
- PET-scan imaging in collaboration with the EORTC Imaging Group;
- Management of liver metastasis from colorectal cancer (CRC);
- Management of elderly patients in collaboration with the EORTC Cancer in the Elderly Task Force;
- Development of a young investigator promotion program.

This plan was designed to improve synergies in the development of innovative concepts.

Achievements and future strategy

Translational research in collaboration with the EORTC Pathobiology and Pharmacology and Molecular Mechanisms Groups.

The quality control tissue microarray testing the influence of fixation time on immuno-histochemical and molecular studies which was presented at ASCO 2005, was used not only to test immunohistochemistry but also fluorescence in situ hybridization techniques (epidermal growth factor receptor) and extractability of DNA and RNA for molecular studies. Cases from this quality control array were last used to test the influence of fixation time on miRNA-extractability with the result that miRNA quality was not affected by different fixation times. A manuscript is in preparation.

Statistical analyses for several TR studies in PETACC 2, a randomized trial studying adjuvant chemotherapy in resected colon cancer, are ongoing. These include:

- retrospective analyses of TS and dUTPase expression in PETACC-2 patients;
- retrospective analyses of TS, MTHFR, OPRT polymorphisms in PETACC-2 patients;
- prognostic impact of KRAS- and BRAF-mutations in UICC stage III colorectal cancer adjuvantly treated with 5 FU-chemotherapy;
- relevance of MSI for prognosis in UICC stage III colorectal cancer adjuvantly treated with 5 FU-chemotherapy;
- relevance of p53, Ki-67 and AMACR for prognosis in UICC stage III colorectal cancer adjuvantly treated with 5 FU-chemotherapy;
- relevance of Hif1a, CXCR4, VEGFD and VEGFC for prognosis in UICC stage III colorectal cancer adjuvantly treated with 5 FU-chemotherapy;
- relevance of pTen for prognosis in UICC stage III colorectal cancer adjuvantly treated with 5 FU-chemotherapy.

SPECTAColor

Since extensive screening is necessary to conduct trials in subgroups of CRC, a screening platform, SPECTAColor, is being initiated with the support of Alliance Boots. Patients presenting with metastatic CRC (or high risk stage III tumors) at the participating centers will consent that their tumor material is centrally characterized for molecular markers by a standardized method. Depending on the results of this screening, therapeutic clinical trials will be offered to the patients fulfilling the molecular inclusion criteria. The screening platform requires a central pathology service unit for central quality control and DNA and RNA extraction from the tumor, and this unit will work closely with the virtual tissue bank at EORTC Headquarters.

PET-scan imaging

Perioperative chemotherapy has a proven benefit in localized gastric cancer and esophago-gastric junction adenocarcinoma, but only about 20% of patients achieve a major histologic response from neoadjuvant chemotherapy. To improve upon this, The GU Group in collaboration with the EORTC Imaging Group propose an imaging sub-study aimed at validating the sensitivity and specificity of the FDG-PET (18F-fluorodeoxyglucose positron emission tomography) based early response test in a multicenter study. Early metabolic response evaluation by FDG-PET allows for an accurate prediction of histo-pathologic response during neoadjuvant chemotherapy, and PET imaging has been shown to have some predictive value in esophago-gastric cancer treated with neoadjuvant chemotherapy, but these have not been validated in a multicenter setting. Such a study is presently in preparation inside of the Group.

EORTC trial 40091 (BOS2) aims to assess the value of three different chemotherapy regimens, FOLFOX + Bevacizumab versus FOLFOX + Panitumumab versus FOLFOX. Alone, in perioperative approach for colorectal cancer patients metastatic to the liver deemed to be resectable. The BOS2 imaging subprotocol's primary endpoint is to examine the NPV of PET assessed tumor FDG uptake response after one course of preoperative chemotherapy on the outcome of neo-adjuvant therapy, measured by structural, radiologically-assessed response rate. Since the US NSABP trial C11 on liver metastasis was prematurely closed due to poor accrual, BOS2 is now the only active protocol in CRC liver metastasis worldwide. A sister protocol for KRAS mutated patient is presently in discussion (BOS3).

EORTC trial 40983 (EPOC) has been re-evaluated for long term results, and an abstract was presented at ASCO 2012. TR is in progress.

The **BOS1 trial** was closed prematurely due to reports from CAIRO 2 and PACCE on the toxicity of dual antibody administration. Clinical data are now available and will be presented with TR data when available.

Management of elderly patients

Based on the clinical and scientific need, we are about to activate a phase II trial in frail patients with metastatic colorectal cancer comparing 5Fu/LV alone and in combination with cetuximab. This trial is a collaborative effort between the EORTC Cancer in the Elderly Task Force and the GI Group and can serve as a pilot protocol in which we integrate specific elderly related tools. It opens also the opportunity to generate scientific data in a population that in most cases is excluded from clinical trials.

Development of a young investigator promotion program

The GI Group has launched a Young Investigator's (YI) promotion program whose aim is to identify and attract promising European YIs to the GI Group, improve interactions with YIs in national groups, strengthen the long-term affiliation to the GI Group, better develop the GI Group as a lively forum of discussion, and increase the number of participating sites for GI Group trials. The first "young investigator" has been chosen this year for a three year fellowship, and it is planned to select one new candidate each year.

Protocols activated before 2011

- **EORTC trial 40054-22026 PETACC-6** is a study of perioperative chemoradiotherapy in locally advanced rectal cancer, opened in 2008 with the accrual completed in the Summer 2012 with a total of 1094 patients (100.4% of planned accrual and achieved ahead of schedule) with locally advanced rectal cancer who were randomized between preoperative chemo-radiotherapy and postoperative chemotherapy with capecitabine and oxaliplatin (investigational) and with capecitabine alone (standard). The primary endpoint is disease free survival.

Protocols activated in 2011-2012

- **EORTC trial 40071**: Effectiveness of first line treatment with lapatinib and ECF/X in metastatic gastric cancer according to HER2 and EGFR status: a randomized phase II trial. About 480 patients with adenocarcinoma of the stomach or eso-gastric junction who were not amenable to curative surgery and who did not receive prior palliative CT will be screened centrally for HER2/EGFR1 by FISH and IHC. Patients are enrolled into one of two strata: HER2 FISH- and IHC 2/3+, or HER2 IHC 0/+ and EGFR1 FISH+ or IHC 2/3+.

Hepatocellular carcinoma guidelines

The GI Group and the European Association for the Study of the Liver (EASL) published joint Clinical Practice Guidelines on the management of hepatocellular carcinoma (HCC) (J Hepatology 2012;56(4):908-943; Eur J Cancer 2012;48(5):599-641). These EASL-EORTC guidelines define the use of surveillance, diagnosis and therapeutic strategies recommended for patients with HCC.

www.eortc.org/research-groups/gastrointestinal-tract-cancer-group

Structure of the Group

Chair **B. Tombal, Brussels (BE)**

A team comprised of A. Bex, N. Clarke, C. Sternberg and B. Tombal is leading the Genito-Urinary Cancers Group (GU Group), and a strategic plan to re-dynamize genitourinary cancer research activity has been accepted by the EORTC Scientific Audit Committee (SAC).

Recent Achievements

Testicular cancer

The results of the randomized phase III **EORTC 30983** study comparing paclitaxel-bleomycin, etoposide, and cisplatin (BEP) to standard BEP in intermediate-prognosis germ-cell cancer have been published (*J Clin Oncology* 2012;30(8):792-7999). The study shows that T-BEP administered with granulocyte-colony stimulating factor (G-CSF) seems to be a safe and effective treatment regimen for patients with intermediate-prognosis germ cell cancer. Unfortunately, the study recruited a smaller-than-planned number of patients and included 7.7% ineligible patients, so that the trial could not demonstrate statistical superiority of T-BEP for progression-free survival (PFS).

The GU Group has released the results of the randomized phase III **EORTC 30974** study comparing standard dose BEP with sequential high-dose cisplatin, etoposide, and ifosfamide (VIP) plus stem-cell support in males with poor-prognosis germ-cell cancer (Ann Oncol 2011;22(5):1054-1061). In addition, the GU Group has contributed to two other publications (J Natl Cancer Inst 2011;103: 241-249, J Clin Oncol 2011;29(8):957-962).

Muscle invasive and metastatic bladder cancer

The randomized phase II/III **EORTC 30986** trial assessing gemcitabine/carboplatin and methotrexate/carboplatin/vinblastine in patients with advanced urothelial cancer who are unfit for cisplatin-based chemotherapy has been published (*J Clin Oncol* 2012;30(2):191-199). This is the first randomized phase II/III trial comparing two carboplatin-based chemotherapy regimens in patients with urothelial cancer who are ineligible ("unfit") for cisplatin chemotherapy. There were no significant differences in efficacy between the two treatment groups. The incidence of severe acute toxicities was higher for those receiving M-CAVI.

The GU Group has also released the results of the randomized phase III **EORTC 30987** study comparing paclitaxel/cisplatin/gemcitabine and gemcitabine/cisplatin in patients with locally advanced or metastatic urothelial cancer without prior systemic therapy: (*J Clin Oncol* 2012 **30**(10):1107-1113). The study showed that the triplet was well tolerated but did not add to the standard chemotherapy regimen in terms of a better outcome indicating that novel targeted drugs need to be considered in order to improve the outcome of metastatic bladder carcinoma patients. The group is waiting the results of the transitional research component.

The long-term results of the international phase III **EORTC 30894 BA06** trial assessing neoadjuvant cisplatin, methotrexate, and vinblastine chemotherapy (CMV) for muscle-invasive bladder cancer have been published (J Clin Oncol 2011;29(16):2171-2177). The study concludes that CMV

chemotherapy improves outcome as first-line adjunctive treatment for invasive bladder cancer. This is the second large randomized trials that confirm a statistically significant and clinically relevant survival benefit.

Non Muscle Invasive Bladder Cancer

The phase II **EORTC 30993 trial**, Sequential intravesical chemoimmunotherapy with mitomycin C (MMC) and bacillus Calmette-Guérin (BCG) and with bacillus Calmette-Guérin alone in patients with carcinoma in situ of the urinary bladder, has been published (*Eur Urol* 2011;**59**(3):438-446). That study demonstrates that in the treatment of patients with bladder carcinoma *in situ*, sequential chemo-immunotherapy with MMC plus BCG has acceptable toxicity. The reported complete remission and disease-free rates were similar to those on BCG alone and to previous publications on sequential chemo-immunotherapy.

The final results of **EORTC trial 30962**, Bacillus Calmette-Guerin: One-third dose versus full dose and one year versus three years of maintenance, have been presented at an international meeting, and a manuscript has been submitted for publication. The study concludes that patients receiving three years full dose of BCG had the highest disease free rate at five years while those receiving 1/3 dose for one year had the lowest. Superiority could not be formally concluded for either comparison. There were no differences in progression, survival or stopping treatment for toxicity.

In addition, the group has contributed to other publications (Int J Urol 2011;18(2),113-120, Eur Urol 2011;59:997-1008, Eur Urol 2011;59:584-594, Eur Urol 2011;60: 431-434, Eur Urol 2011;59(3):374-376).

Prostate cancer

The long-term results of **EORTC trial 22911**, Immediate post-operative radiotherapy after radical prostatectomy in pT3N0 prostate cancer, have been presented at several international meetings and has been accepted for publication. The study investigates the value of immediate adjuvant irradiation after prostatectomy for patients presenting postoperatively with pathological factors indicative of a high risk of relapse. The study failed to show significant benefit on overall survival, therefore questioning the exact role of adjuvant radiotherapy.

Long term results with 12.9 years of median follow-up of **EORTC trial 30891**, Immediate or deferred androgen deprivation for patients with prostate cancer not suitable for local treatment with curative intent, have been updated. The long-term analysis has been submitted to several international meetings.

EORTC trial 30985, an intergroup phase III study with SWOG 9346, Intermittent *versus* continuous androgen deprivation in hormone sensitive metastatic prostate cancer patients, has been analyzed and was presented at ASCO 2012. This study shows that intermittent androgen deprivation therapy is inferior to continuous treatment in patients with metastasis. A manuscript has been submitted for publication.

Renal Cell carcinoma

EORTC trial 30012, conducted together with the MRC (MRC RE04) and which compared interferon-alpha, IL-2 plus 5-FU to interferon alone, has been published (*The Lancet* 2010; 375(9715):641-648). Although the study shows that the combination therapy does not improve overall or progression-free survival compared with interferon alfa-2a alone, it suggests that immunotherapy might still have

a role because it can produce remissions that are of clinically relevant length in some patients. Identification of patients who will benefit from immunotherapy is crucial.

The final analysis of **EORTC trial 30904** comparing radical nephrectomy to elective kidney sparing surgery in 541 low stage patients with renal cell carcinoma has been completed and found no significant difference in efficacy in the target population of clinically and pathologically eligible patients (*Eur Urol* 2011;59(4):543-552).

Ongoing and Future trials

Prostate carcinoma

The phase III **EORTC 30041-22043** trial is the follow-up of **EORTC trial 22911** and looks at adjuvant radiotherapy with or without six months of hormonal therapy in prostate carcinoma patients with positive surgical margins following radical prostatectomy. Following the results of EORTC trial 22911 that failed to show significant benefit in time to metastasis and overall survival, a paradigm shift has occurred amongst European urologist toward delay salvage radiotherapy. This has impacted negatively the recruitment of the trial. Consequently EORTC 30041-22043 has been amended to allow inclusion of salvage treatment.

The GU Group has joined the Prostate Cancer Consortium in Europe (PEACE) trial (**PEACE 1),** A prospective randomized phase III study of androgen deprivation therapy with or without local radiotherapy with or without abiraterone acetate and prednisone in patients with metastatic hormone-naïve prostate cancer. This multi-center phase III study will address two important questions: the role of local radiotherapy and of abiraterone acetate in patients with metastatic hormone-naïve prostate cancer. The study will incorporate transitional research on imaging of bone metastases in collaboration with the EORTC Imaging Group.

EORTC trial 1211, Phase II randomized comparative trial testing TAK-700 (Orteronel) *versus* bicalutamide in metastatic prostate cancer patients failing first line treatment with luteinizing hormone releasing hormone (LHRH) agonists, will be launched at the fourth quarter of 2012 or first quarter of 2013. The main objective of the trial is to assess the anti-tumor activity of bicalutamide and TAK-700 in terms of clinical progression-free survival. TAK-700 is a selective non-steroidal inhibitor of 17,20 lyase.

The first meeting of the multidisciplinary clinic-genomic platform for high-risk prostate cancer has been discussed.

Bladder carcinoma

At present there are no new studies in non-muscle invasive bladder cancer (NMIBC), but evaluation of closed studies is ongoing and several manuscripts are in preparation.

Funding is being sought for a TUR quality control study, the **EORTC 30082 trial**.

In the phase I **EORTC 30061 trial**, the standard chemotherapy regimen +/- lapatinib, a dual Her-1 and Her-2 blocker, is being investigated to determine whether the addition of a novel targeted agent will contribute to the outcome of advanced bladder cancer patients.

Renal Cell carcinoma

The **MRC/EORTC 30072 (SORCE)** trial is being conducted in EORTC sites in The Netherlands and Belgium. This trial investigates the role of adjuvant treatment with sorafenib in intermediate and high-risk patients.

The **EORTC SURTIME 30073** trial is now recruiting. Pre-surgical sunitinib followed by nephrectomy and sunitinib *versus* nephrectomy followed by sunitinib, is a randomized phase III trial assessing the timing of radical nephrectomy in patients with synchronous metastatic renal cell carcinoma.

Projects & Strategies for the coming years

An action plan has been submitted to the SAC for the rebuilding of the GU activities.

The key actions are:

- Modify the organization and leadership of the GU Group. Trial steering committees involving the principal investigators (PI), a member of GU Group Executive Committee if not the PI, and EORTC Headquarters statistics representatives will play the central role in developing the work of the group. Monthly telephone conferences and bi-annual face-to-face meetings with the GU Group Executive Committee will be conducted for each trial.
- Review of previous GU Group activities.
- Reconstruct the GU Group membership's recruitment capabilities based on a limited number of strategic trials that have been already designed and approved.
- Ensure a series of publications in peer reviewed journals by identifying important research questions that can be answered using large datasets from GU Group studies that have been completed in the last few years.
- Build a membership of new investigators, especially, through prospective clinico-genomic and imaging based trials.
- Revisiting clinical trials addressing rare tumor types.

Translational research

Functional Imaging

In prostate cancer, for instance, there is a clear need to develop ways of measuring metastatic spread to the bone in high risk patients in relatively early stages of the disease as well as better measuring responses in more advanced disease through, for example, developing and validating skeletal magnetic resonance imaging (MRI) and by identifying bone and other biomarkers.

Translational research grant

The GU was awarded a grant from the EORTC Board for a project studying skeletal MRI in patients with prostate cancer. This project will study the role of axial skeletal MRI compared to traditional bone scan in evaluating patients with prostate cancer and assess if this imaging modality can be used for modifying RECIST to determine response to treatment.

Collaboration with other Groups (EORTC and others)

Other EORTC Groups

The long-standing successful collaboration with the EORTC Radiation Oncology Group will be continued in yet another large trial in prostate cancer patients (**EORTC trial 30041-22034**, M. Bolla and S. Joniau are the principal investigators).

The high-risk prostate cancer platform will be conducted in collaboration with EORTC Radiation Oncology, Imaging, and Pharmacology and Molecular Mechanisms Groups.

Medical Research Council (MRC) and other global Cooperative Groups

The existing close collaboration with the MRC will be continued (SORCE trial).

www.eortc.org/research-groups/genito-urinary-cancers-group

Structure of the Group

Chair	**A. Casado, Madrid (ES)**
Secretary	**P. Ottevanger, Nijmegen (NL)**
Treasurer	**I. Vergote, Leuven (BE)**

Executive Steering Committee	A. Casado, Madrid (ES) N. Reed, Glasgow (UK) P. Ottevanger (NL) I. Vergote, Leuven (BE) A. Ferrero, Torino (IT) F. Mota, Coimbra (PT)
Clinical Research Physician	D. Lacombe, Brussels (BE)
Statistician	C. Coens, Brussels (BE)
Translational Research	S. Scholl, Paris (FR) E. Berns, Rotterdam (NL)
Young Investigator	I. Boere, Rotterdam (NL)
Ad hoc person	D. Katsaros, Torino (IT)

Tumor Site Committees and other committees	
Cervix and Vulva	A. Ferrero, Torino (IT)
Endometrium	F. Mota, Coimbra (PT)
Ovary	P. Ottevanger, Nijmegen (NL)
Translational Research	S. Scholl, Paris (FR) E. Berns, Rotterdam (NL)
Quality control	N. Reed, Glasgow (UK)
Quality of life	E. Greimel, Graz (AT)
Surgery	S. Greggi, Naples (IT)
Radiation	E. van der Steen, Arnhem (NL)
Chemotherapy	N. Reed, Glasgow (UK) M. Huizing, Antwerp (BE)

The EORTC Gynecological Cancer Group (GCG) is a multi-disciplinary clinical disease orientated group composed of gynecological oncologists, clinical/medical oncologists, scientists, radiation oncologists and pathologists together with a number of data managers/trial coordinators and nurses from approximately 92 centers across Europe and other countries. The GCG has conducted more than 60 large clinical trials in a variety of gynecologic cancers over the last 35 years (A. Casado et al. EJC (Suppl. 9) 2012: 2:65-73).

Recent achievements

One study currently open to patient entry, the **EORTC 55994** trial, is investigating the role of neoadjuvant chemotherapy followed by radical hysterectomy and lymph node dissection versus concomitant chemo/radiation in early/intermediate cervical cancer. This important study is likely to significantly impact future practice internationally. This study has passed the milestone of 560 patients accrued out of the planned 686 patients. The results of this Trial will be awaited with considerable expectation.

The EORTC 55041 first line trial, comparing standard chemotherapy versus combination chemotherapy and maintenance Erlotinib (Tarceva ©), which was conceived in 2003-2004, was closed on 19 February 2008. This study was one of the first randomized trials in ovarian cancer testing a new biological agent in the first line setting. High-quality, well designed translational research projects have been associated with this trial, and the clinical results have recently been presented during the gynecological oral session at ASCO 2012.

In September 2010, the landmark EORTC 55971 trial, conventional surgery followed by chemotherapy with or without interval debulking compared with neoadjuvant chemotherapy and delayed primary surgery in Stage IIIC and Stage IV ovarian cancer, was published (N Engl J Med 2010;363(10):943-953). Based on this platform, new comprehensive trials are currently being developed with novel targeted agents for use in this group of patients with Stage IIIC and IV disease. There is a unique opportunity to collect tissue specimens before and after therapy and also to evaluate complex functional imaging techniques.

Results of another landmark trial, EORTC 55955-MRC OV05, a randomized trial in relapsed ovarian cancer of early treatment based on confirmed elevation of CA125 versus delayed treatment based on clinical relapse, showed that there is no evidence of a survival benefit or better quality of life with early treatment of relapse based on a raised CA125 level alone (Lancet 2010;376(9747):1155-1163).

Over the past three years, the GCG has been focusing on conceiving and creating its own portfolio of trials. There are currently several projects at various degrees of development:

- EORTC trial 55092: Phase IB-II, open label, multicenter feasibility study of pazopanib in combination with Paclitaxel and Carboplatin in patients with platin-refractory/resistant ovarian, fallopian tube or peritoneal carcinoma. A PET fluciclatide sub-study to the phase II part of the protocol in a limited number of centers has also been initiated.
- EORTC trial 55102: A phase III trial of postoperative chemotherapy or no further treatment for patients with stage I-II medium or high risk endometrial cancer. This study will be an international collaboration with the Nordic Society of Gynecological Cancer (NSGO) and other international gynecological cancer platforms, and it will certainly have an impact on clinical practice. This is the first study in which the validated EORTC Endometrial Module (EN-24) will be applied.
- EORTC trial 55112-62111. Efficacy of aromatase inhibitors in primary advanced or recurrent endometrial stromal sarcoma: a phase II trial.
- EORTC trial 62113-55115. EORTC/CRUK/NCI proposal on high grade undifferentiated sarcoma (HGUS): A randomized phase II study evaluating the role of maintenance therapy with pazopanib in HGUS after stabilization or response to chemotherapy in metastatic first line treatment.

Future Directions and Strategies

The multidisciplinary GCG currently is dealing with one of the greatest challenges in cancer research which is to discover and establish clinically useful predictive and prognostic factors to identify subgroups of patients based on genomic patterns and activated pathways and design clinical trials appropriate for such subgroups.

Current and future GCG research has to include the validation of prognostic and predictive markers, the identification of novel therapies that target specific pathways, and a better understanding of the molecular basis for resistance. These studies will require the collection of large number of biologic materials, both at time of diagnosis and at time of recurrence and, whenever possible, during treatment. These objectives will not be possible without transversal cooperation within the EORTC framework (the EORTC Pathobiology and Imaging groups, etc.), but also without international cooperation. A high standard of cooperation between industry and academia will also be important.

Through the GCG the EORTC, with its unique multidisciplinary infrastructure and long experience in cancer research, is taking part in international networks such as Gynecologic Cancer Intergroup (GCIG), European Network of Gynaecological Oncological Trial Groups (ENGOT) or European translational research organizations focused on gynecological cancer research on a large scale. Good examples of this intergroup collaboration are the following trials:

- EORTC 55111. INOVATYON trial. A MaNGO/ENGOT-ov5 proposal in intermediate platinum sensitive ovarian cancer patients. This is a Phase III international, randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum.
- EORTC project 1212. Vargatef (BIBF1120) in clear cell ovarian and endometrial cancer (DGCG/NCRI/SGCTG).
- GOG-UC1009/EORTC 55116-62114: A phase III randomized trial of gemcitabine plus docetaxel followed by doxorubicin versus observation for uterus-limited high grade uterine leiomyosarcoma.

International Rare Cancer Initiatives (IRCI)

Intergroup collaboration in clinical and translational research and international contribution to establish the current and future world-wide standards of care is also a priority for the GCG. The GCG has a good track record in rare tumors and will continue working on rare diseases along with international partners. IRCI has recently been established as a platform for future development in rare cancers. Founded by the NCI-USA, the CRUK/NCRI and the EORTC, the main focus thus far has been gynecological sarcomas. EORTC trial 55116-62114/GOG-UC1009, EORTC trial 62113-55115, and EORTC trial 55112-62111 are part of the IRCI initiatives.

Quality Assurance

The Quality Assurance subcommittee within the GCG has reviewed both recent open protocols and historical ones. A quality control and assurance program has been established within different gynecological tumor domains. Several papers have been published looking at general approach to the gynecological oncology population as well as specific topics such as, quality indicators of

radical hysterectomy in cervical and ovarian cancer and the impact of the quality of pathology reports on cancer care.

This subcommittee will continue to have a key role in the next generation of GCG trials.

Translational Research

The GCG Translational Research Subcommittee is a very dynamic and active subcommittee which is currently in the process of working on new EORTC projects and on new proposals in the context of the European networks in translational research. Simultaneously, a future thrust of the group led by Dr. Els Berns (Rotterdam) has been in looking at molecular signatures and other molecular markers which may identify adverse risk patients or predict responses to treatment. The group has also increased the annual commitment of support for translational research. The translational research work of Dr. Jozien Hellemans was recognized through various publications about the mechanisms of chemotherapy resistance of ovarian cancer. Dr. Evelyn Despierre from Leuven is currently working on two translational research projects based on the EORTC 55971 and 55041 trials. An outstanding international translational research meeting has been organized by Dr. Suzy Scholl in Paris in October 2012 which will be a turning point in terms of international collaboration.

Collaboration with other EORTC groups

In addition to the encouraging collaboration with the sarcoma group in IRCI, the GCG is well represented in transversal groups within the EORTC. Dr. Els Witteveen from Utrecht was appointed as GCG representative for the Cancer in the Elderly Task Force, and Dr. Els Berns (Rotterdam) is a full member of the EORTC Pathobiology Group. The GCG is also interested in collaborating with the recently created EORTC Imaging group. Collaboration with the EORTC Quality of Life Group resulted in the publication of the validated endometrial module (EN-24) questionnaire by Dr. Eva Greimel and her coworkers. Dr. Greimel has also been fully involved in the analysis and publication of the quality of life sub studies that have been linked to GCG trials such as the 55971 and 55041. A new vulva cancer quality of life module is currently under development with the involvement of GCG members.

www.eortc.org/research-groups/gynecological-cancer-group

Structure of the Group

Chair	**L. Licitra, Milan (IT)**
Secretary	**R. Knecht, Hamburg (DE)**
Treasurer	**G. Andry, Brussels (BE)**

Subcommittee Chairs	
Chemotherapy	J. Buter, Amsterdam (NL)
Radiotherapy	M. Sen, Leeds (UK)
Surgery	C.R. Leemans, Amsterdam (NL)
Translational Research	A. Psyrri, Athens (GR)
Quality of Life	S. Singer, Leipzig (DE)
Young Oncologist/Scientist	S. Oosting-Lenstra, Groningen (NL)

Recent Achievements

- Larynx preservation according to EORTC strategy is state of the art treatment. The EORTC Head and Neck Cancer Group (HNCG) was a pioneer in the field of organ preservation starting with the initiation of the first larynx preservation trial in 1989. **EORTC trial 24891** compared PF (cisplatin and 5-FU) induction chemotherapy followed by radiation therapy (RT) versus total laryngectomy, radical neck dissection, and postoperative RT in patients with hypopharyngeal cancer (J Natl Cancer Institute 1996;88:890-899). A recently published ten year follow up study confirmed that the larynx preservation strategy provides similar overall survival rates as compared with conventional treatment with total laryngectomy and allowed two third of the survivors to retain their larynx (Ann Oncol doi:10.1093/annonc/mds065).
- Locally advanced setting. EORTC neoadjuvant triple drug (Docetaxel, cisplatin and 5-FU) is standard treatment in locally advanced unresectable tumors and for larynx preservation. The role of chemotherapy was radically changed in head and neck cancers following publication of the **EORTC 24971 trial** (N Engl J Med 2007;357(17):1695-1704). In this study, the role of neoadjuvant chemotherapy (NACT) was evaluated in patients with non-resectable locally advanced head and neck cancer. Patients were randomly assigned to receive PF based NACT or TPF (Docetaxel, cisplatin and 5-FU) based NACT followed by RT alone. TPF-NACT showed superior outcome with regard to locoregional tumor control and survival in comparison with the PF NACT regimen and was shown to have a better tolerance and quality of life. The long term follow up with a median of eight years was presented at ASCO 2011 (J Clin Oncol 2011;29(15):367s, abs. 5530).
- High risk patients. **EORTC trial 22931**: Postopertaive combined chemoradiation approach (N Engl J Med 2004;350(19):1945-1952). In this study postoperative concurrent administration of high dose cisplatin with postoperative radiotherapy was proven to be more efficacious than radiotherapy alone in patients with locally advanced head and neck cancer without an undue number of late complications.
- Building upon previous results. EORTC trial 24061: In this phase II study, the feasibility and efficacy of four cycles of TPF regimen combined with the EGFR inhibitor cetuximab followed by the

concomitant use of radiotherapy and one platinum compound, cisplatin or carboplatin (for radio sensitization), plus cetuximab was being studied. This trial was closed in 2010 after recruitment of 47 patients due to an unexpectedly high rate of toxicities, and the results will be published soon. **Phase I/II EORTC trial 24051**: induction chemotherapy followed by chemoradiation with or without lapatinib, a dual EGFR/ErbB2 kinase inhibitor, in patients with locally advanced larynx and hypopharynx squamous cell carcinoma. This trial was opened in 2007 and enrolled seven patients, however the trial was stopped due to toxicity.

- Innovative drug development in head and neck cancer: a new highly integrated multidisciplinary platform. **EORTC trial 90111-24111**: Neoadjuvant afatinib based treatment strategies followed by surgery in squamous cell carcinoma of the head and neck: an EORTC NOCI-HNCG window study. This concept study evaluates the strategy of evaluating the activity of targeted agents using molecular imaging techniques like FDGPET. It is a proposed to include other targeted agents to be tested in this neoadjuvant setting.

Projects/Strategies for the coming years

- Rare tumors initiative. The HNCG wants to address the treatment of rare tumors in the head and neck using novel treatments. In this direction, **EORTC trial 1206**, a randomized phase II study to evaluate the efficacy and safety of chemotherapy versus androgen deprivation therapy in patients with recurrent and/or metastatic, androgen receptor expressing, salivary gland cancer, is being initiated.
- HPV positive tumors. It is becoming widely accepted that human papilloma virus (HPV) induced tumors of the head and neck vary in their biology and response to treatment. This is a sub group that has a consistently increasing incidence with a good prognosis. Consequently ,there are initiatives to reduce the intensity of standard treatment so as to decrease the toxicity. There are also proposals to try HPV vaccines as well. The HNCG holding discussiond with a vaccine company to initiate a phase II study.
- Recurrent/metastatic setting. There are currently proposals in this setting, under discussion with companies.

Translational research

The HNCG is strongly focusing on translational research projects. The HNCG is in the position to have access to extended clinical data of a number of databases of prospective randomized studies that could be used for translational research purposes. The group took actions to actively involve investigators in the field of preclinical and translational research in the group activities and meetings, and this led to three different translational research projects that are currently in development. The HNCG plans to explore whether tumor HPV DNA and p16 protein status is predictive of response to docetaxel in the cohort of patients treated within the **EORTC 24971/TAX323 phase III clinical trial**. In addition, functional p53 status and b-tubulin expression status will be correlated with treatment outcome to see whether these biomarkers have the potential to be used as prognostic factors.

Another research project aims to evaluate the association of excision repair cross complementation group (ERCC1) expression with therapeutic response and survival among patients treated with postoperative irradiation with or without concomitant cisplatin in the **EORTC 22931 phase III clinical trial**. In this same trial the available specimens will be used to create TMA to validate chemoradiation signature that are already available.

A strong TR component is also present in the study proposal granted by NOCI in 2010. This is a window study in patients affected by locally advanced HNSCC that is deemed to be treated by surgery. The patients will be treated with the administration of an EGFR inhibitor and other targeted agents before surgery, and the activity of the drugs will be evaluated with advanced imaging technique and analysis of the different downstream molecular pathways to explain tumor response and resistance mechanisms. Functional magnetic resonance imaging standards will be set up within this trial.

Collaboration with other groups

Joint sessions with the EORTC Radiation Oncology Group (ROG) during the EGAM meetings are currently standard. A fruitful discussion with the members of the ROG resulted in the previously mentioned common proposals with this group. In addition, a number of meetings have taken place between representatives of both groups which resulted in new plans for future collaborations. Formal collaboration also exists with the GETTEC (Grouped'Etude des Tumeurs de la Tête et du Cou), and representation at each other's meetings has been arranged.

As previously mentioned, the HNCG is working towards improving collaborations with other EORTC groups, especially the Imaging and Pathobiology groups. Collaborations are also foreseen with the Cancer in the Elderly Task Force as well as the Infectious Diseases Group.

www.eortc.org/research-groups/head-and-neck-cancer-group

Structure of the Group

Chair	**N. DeSouza, Sutton (UK)**
Secretary	**N. Nestle, Freiburg (DE)**
Treasurer	**O.S. Hoekstra, Amsterdam (NL)**
Vice-Chair	S. Stroobants, Edegem (BE)

Imaging data have the potential to provide information on disease profiling pertaining to diagnosis, prognosis, selection of therapy, monitoring of response to therapy and pharmacokinetic information of drugs. The Imaging Group (IG) operates to establish and maintain the scientific and clinical value of advanced imaging. Moreover, the IG has and will develop specific analytical and review procedures as well as quality control procedures, in the context of clinical trials conducted by the EORTC groups.

The main foci of IG activities are:

- Liaising with EORTC Disease Oriented Groups concerning imaging in clinical studies;
- Conducting scientific research projects:
  - The Innovative Medicine Initiative QuIC-ConCePT (Quantitative Imaging in Cancer: Connecting Cellular Processes with Therapy) project;
  - Developing a "RECIST" (Response Evaluation Criteria In Solid Tumors) equivalent for bone metastases.

Achievements

Optimal image quality is essential both for visual interpretation as well as for quantification of PET images. The European Association of Nuclear Medicine (EANM) guideline for quantitative FDG PET/CT studies provides minimal standards for patient preparation and scan acquisition, and proposes specific quality control measures for harmonizing scanner performance (*Eur J Nucl Med Mol Imaging* 2010;**37**(1):181-200). A European accreditation system to implement the EANM guideline and the quality control (QC) procedures was set up and is run under the direction of EARL (European Association of Nuclear Medicine Research Ltd.) and the EORTC.

Within the QuIC-ConCePT project the IG is undertaking a quality assurance exercise for diffusion-weighted MRI and ^{18}FLT PET which can subsequently be implemented in other EORTC clinical studies. Appropriate phantoms for measurement of system stability and reproducibility for these imaging methods have been developed, and the group is now embarking on protocol optimization and standardization for data acquisition.

Imaging within EORTC studies

The IG provides scientific supports to the disease oriented groups, when imaging is implemented in the trials. IG is responsible for the study design when imaging is a sub-study. To ensure of obtaining good quality images, IG provide imaging guidelines for acquisitions and quality control procedure in align with the main study objectives. Furthermore, it has begun organizing prospective quality

control review of the imaging scans within EORTC studies. Trials that are currently being considered include:

- **EORTC trial 26091** (Quality Control performed by EORTC Imaging Officer, Central Review performed by Marion Smits of the Daniel den Hoed Cancer center in Rotterdam).
- **EORTC trial 26101** (Quality Control performed by the Independent Review Board of MRI Tumor Imaging in the Department of Neuroradiology of the University Hospital, Heidelberg, Germany and double checked by the EORTC Imaging Officer).
- **EORTC trial 90111** (PET Quality Control performed by EORTC Imaging Officer, MRI Quality Control performed by the team of Paolo Potepan Fondazione IRCCS Istituto Nazionale dei Tumori in Milan).
- **EORTC trial 20101** (PET/CT QC performed by EORTC Imaging Officer, and backup by the laboratory of Wim Oyen at the Nijmegen University Medical Center).
- **EORTC trial 40091** (PET/CT imaging sub-study QC performed by EORTC Imaging Officer).
- **EORTC 1211** (Axial Skeleton MRI imaging sub-study QC performed by the MRI imaging study coordinator).
- **EORTC 90101, NOCI trial** (CT and/or MRI QC performed by the EORTC Imaging Officer).
- **EORTC trials 26091 and 26101** include brain MRI imaging guidelines sign off by the local radiologist/neuroradiologist, prospective QC, central review of all brain MRI scans;
- **EORTC 20101 (H11)**: FDG-PET/CT and diagnostic CT – sign off on imaging guidelines, dummy run, prospective QC of scans, central review of the baseline and after one cycle chemo.
- Extensive quality assurance with respect to imaging has been implemented in **EORTC trial 90111**. Each site is asked to sign off on standardized imaging guidelines, dummy run to warrant site activation, and FDG-PET/CT accreditation for a quantitative FDG-PET/CT.
- **EORTC trial 40091 (BOS2)**: FDG-PET/CT – sign off on imaging guidelines, FDG-PET/CT accreditation, dummy run, prospective QC of scans, central review of all PET/CT & CT scans for the FDG sub-study. The main objective of the imaging sub-study is to investigate separately in the three arms of the trial the Negative Predictive Value (NPV) of change in FDG uptake at day 14, cycle 1 of neoadjuvant chemotherapy relative to baseline, against a radiological response (RECIST 1.1) measured after three cycles.
- **EORTC 1211** (AS-MRI): Axial Skeleton MRI – sign off on imaging guidelines, dummy run, prospective QC of scans, central review of all MRI, PET Bone scans, CT & MRI of chest, abdomen, pelvis, x-rays.
- **EORTC 90101** (CREATE): CT/MRI – sign off on imaging guidelines, Quality Control performed by EORTC Imaging Officer: dummy run, prospective QC of scans, central review of CT and/or MRI of any anatomy coverage.

The IG has finalized the minimum levels of QA/QC of scans.

- **Level 1** – imaging guidelines signature page which is to be signed by the site's responsible radiologist and/or nuclear medicine physician indicating that they agree with the proposed imaging guidelines and will implement these for all patients in the respective study for all subsequent visits.

- **Level 2** – dummy run – a test scan which warrants the site's activation. The sites are required to submit a scan in compliance with the provided imaging guidelines. The scan is reviewed by the EORTC Imaging Officer for compliance and technical adequacy and not analyzed further.
- **Level 3** – FDG-PET/CT scanner accreditation. In collaboration with national and international accrediting bodies, e.g. EARL FDG-PET/CT Accreditation program, the EORTC strives to ensure harmonization of the PET/CT scanners for studies with quantitative FDG end points.
- **Level 4** – prospective quality control – done on an ongoing basis for all scans submitted to the EORTC either *via* the EORTC Imaging Platform or *via* CD/DVD. Sites are notified rapidly of non-compliance.
- **Level 5** – central review.

Innovative Medicines Initiative QuIC-ConCePT project

Partcipation in the Innovative Medicines Iniatiative QuIC-ConCePT project is an important activity of the IG. QuIC-ConCePT aims to qualify imaging biomarkers of tumor cell proliferation, apoptosis, and necrosis that will allow drug developers to reliably demonstrate the modulation of these pathologic processes in patients with malignant tumors in clinical trials. The IG is involved in the overall management of the project and also plays a central role the conduct of the clinical research work package. The following three protocols are in development for inclusion in the QuIC-ConCePT project

In collaboration with the EORTC Gastrointestinal Tract Cancer Group, **EORTC trial 40091 (BOS 2) and EORTC trial 1207 (BOS 3)**: two randomized phase II trials evaluating the efficacy of FOLFOX alone, FOLFOX plus bevacizumab, and FOLFOX plus panitumumab in kras wildtype (BOS2), and evaluation the efficacy of FOLFOX alone and FOLFOX plus Aflibercept in kras mutant (BOS3) as perioperative treatment in patients with resectable liver metastases from colorectal cancer. The primary end-point of the imaging sub-study is the correlation between the change in IB after one cycle with the pathological response (% change of viable cells in surgical resection specimen) and to define the threshold for non-response. Design: 2x baseline FLT-PET and DW-MR; 1 FLT-PET and DW-MR after one cycle and prior to surgery

In collaboration with the EORTC Lung Cancer Group, **EORTC trial 1217**: a phase II trial in neo-adjuvant/adjuvant setting where patients will receive the standard of care (vinorelbine/ cisplatin) in non-small cell lung cancer patients with non-squamous histology. The primary end-point of the trial is the correlation between the change in IB after one cycle with the pathological response (% change of viable cells in surgical resection specimen) and define the threshold for non-response. Design: 2x baseline FLT-PET and DW-MR; 1 FLT-PET and DW-MR after 1 cycles and prior to surgery.

RECIST equivalent for bone metastases

The IG has established a committee whose aim is to achieve guidelines for imaging bone and to create some sort of RECIST equivalent for the assessment of bone metastases that can be used in EORTC clinical trials. This committee is composed of specialists in both radiology and nuclear medicine and met for the first time in September 2012 to review the current state of the art, discuss the limitations and pitfalls, and devise a strategic plan.

www.eortc.org/research-groups/imaging-group

Structure of the Group

Chair	**P. Donnelly, Nijmegen (NL)**
Secretary	**M. Bassetti, Genova (IT)**
Treasurer	**O. Marchetti, Lausanne (CH)**
Other members	C. Cordonnier, Creteil (FR) P. Verweij, Nijmegen (NL) L. Pagano, Rome (IT)
Young Scientist	M. Bassetti, Genova (IT)

The Scientific Committee comprises the Chair, the Trial Coordinators, the Data Review Committee Coordinators, the Clinical Research Physician, the Statistician, and the Data Manager. M. Paesmans has been officially appointed as the statistician to the EORTC Infectious Diseases Group (IDG).

Recent achievements symposia and meetings

- Joint EORTC/MSG Interactive Symposium session: Defining Invasive Fungal Infections: Challenging the Mycoses Study Group/EORTC Diagnostic Algorithm held during the 48th Annual Meeting of the IDSA, in Vancouver, Canada (October 2010).
- IDG meetings were held in Santorini (October 2009) and in Vienna (April 2010).
- EORTC Workshop "The ins and outs of diagnostic tests" held during the 20th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) Vienna (April 2010).
- EORTC/ESCMID Symposium "Antifungal management strategies during the 21st ECCMID in Milan (May 2011).
- EORTC/ESCMID Symposium "Common statements in the literature regarding invasive fungal diseases – truth or cliché" during the 22nd ECCMID in London (April 2012).
- "Invasive aspergillosis and the EORTC" during the 18th Congress of the International Society of Human and Animal Mycology, Berlin (June 2012).

Projects / Strategies

EORTC trial 65031: Epidemiological study of fungemia in cancer patients. The objective of the study was to assess the incidence, species distribution, risk factors, and outcome of bloodstream fungal infections in cancer patients. The study was activated in 2005 and recruited 304 patients. The final analysis is in progress.

European Conference on Infections in Leukemia (ECIL). This is a collaborative project of the IDG, the Infectious Diseases Working Party (IDWP) of the European Organization for Bone Marrow Transplantation (EBMT), the European Leukemia Net, and the International Immunocompromised

Host Society (ICHS). In September 2009, the 3rd European Conference on Infections in Leukemia took place in Juan-les Pins, France with the themes of updateing of the previous ECILs antifungal guidelines (prophylaxis, empiric treatment, treatment), Zygomycosis, and on non-invasive diagnostic procedures for invasive fungal diseases (IFDs).

Microbiology Reference Laboratories (MRL). The Institute of Microbiology, Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland is the IDG reference center for bacteria and yeasts, and the Department of Medical Microbiology, Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands, is the reference center for filamentous fungi. MRL are in charge of the quality control program regarding species identification and susceptibility testing in ongoing clinical trials of the IDG. They are also in charge of keeping a repository of the microbial strains collected in clinical trials. Instructions for international shipment of microbial strains will be issued in compliance with International Air Transport Association (IATA) regulations.

Future projects

The IDG has a proud history and is following in the footsteps of many illustrious pioneers. Now, as then, we are facing several challenges as a group that will define our future in order to revitalize interest in the scientific community regarding the research and treatment of infectious complications among patients with cancer. Our thrust will be four-fold:

1. Clinical trials - exploratory, observational and intervention;
2. Diagnostic validation and utility studies;
3. Epidemiological studies and, importantly;
4. Education and training which will involve fellowships, training courses, seminars and educational sessions at international conferences including the Trends in Medical Mycology, The European Congress of Clinical Microbiology and Infection and the International Society of Human and Animal Mycology (ISHAM).

Collaborations with other Groups

In order to perform high quality projects likely to have a major scientific impact, the collaboration with other EORTC Groups, particularly with the EORTC Leukemia Group LG), and with other international research organizations active in the field is a top priority. An alliance has been formed between the European Aspergillus PCR Initiative (EAPCRI), a working group of the ISHAM, and the IDWP of the EBMT to help propose and validate a standard for Aspergillus PCR that can be used to screen high-risk patients. This strategy should allow more rapid and efficient recruitment of patients. Contacts have been with the: LG, European Leukemia Net, ICHS, Infection group of the Multinational Association for Supportive Care in Cancer (MASCC), European Confederation of Medical Mycology, and MSG.

It is essential to conduct high quality clinical trials addressing clinically relevant issues for the prevention, diagnosis, and management of infections among cancer patients and to create a seamless interaction between the IDG, EORTC Headquarters, other organizations with a shared interest, and potential study sponsors. The Early Project Optimization Department (EPOD) and the Medical Department at EORTC Headquarters will help assist in study design, protocol development, assessment of feasibility, and allocation of resources.

Ongoing projects

EORTC trial 65091: Empirical versus pre-emptive antifungal therapy in patients with hematological malignancies. A therapeutic phase III strategy study (joint effort with the LG, ISHAM- EAPCRI, and EBMT-IDWP). In this project there is a strong component of translational research including the validation of a standardized aspergillus PCR proposed by the ISHAM-EAPCRI, the Validation of beta-D-glucan for the early diagnosis and follow-up of IFDs and the validation of potential genetic single nucleotide polymorphisms (SNPs) signatures associated with the development of IFDs. The trial is currently actively recruiting.

MSG005: Re-categorization of the cases of the Global Comparative Aspergillus study: a project of EORTC / MSG collaborative analysis.

Research projects in development

Refining the EORTC/MSG definitions of invasive fungal diseases.

The development of the 2008 EORTC/MSG definitions of invasive fungal disease will be continued and working groups has been established for the following topics: 1) Guidance on imaging, 2) Update of galactomannan especially for BAL, 3) PCR update, 4) Beta-D-Glucan, 5) Tissue diagnosis, 6) Inclusion of patients in the ICU, 7) Pediatrics, 8) Pneumocytosis, 9) Cryptococcosis , 10) Endemic mycosis.

The Chairs of the IDG and MSG will lead the process, and there will be equal representation from both groups. Working groups of three to five experts drawn from both the EORTC and MSG will be convened to review the literature and make recommendations on their topic, and present them to the EORTC and MSG for approval.

Observational studies under the auspices of the EORTC

The PICNICC Study, Predicting Infectious Complications of Neutropenic Sepsis In Children with Cancer, is a study run by Drs Bob Philips and Lesley Stewart of the University of York, United Kingdom and comprises a meta-analysis using individual patient data. The aim is to construct models for predicting complications with outcomes being death, admission to intensive care unit, need for moderate organ support, and documentation clinically and microbiologically documented infections. The data from trial XIV (Cometta et al, CID, 2003; 37: 382-389) has been extracted by Marianne Paesmans and will be included in the analysis.

RIFIFI Study: Risk Identification For Invasive Fungal Infection, was initiated by Drs J. Klastersky, P. Donnelly, R. Feld and Ben De Pauw and designed as an observational study of patients with febrile neutropenia and a further expected duration of febrile neutropenia > 10 days (essentially hematological patients). The aim of the study is to construct a model for identifying patients who will develop a fungal invasive infection. The data are currently being analyzed and will be reported shortly.

Exploratory studies

Developing pharmacokinetic profiles of antimicrobial drugs to optimize therapy of patients who develop infections whilst undergoing chemotherapy for cancer or receiving a stem cell transplant.

Diagnostic validation and utility studies

Prospective study to explore inflammatory markers e.g. CRP and indicators of toxicity, citrulline for their potential utility as specific risk factors for infection (joint effort with the EORTC Leukemia Group, the Infection Group of the MASCC, and the EBMT-IDWP).

Establishing the optimal sampling conditions, diagnostic accuracy and clinical utility of blood cultures (joint effort with the EORTC Leukemia Group, the Infection group of the MASCC, and the EBMT-IDWP).

Prospective study to explore prognostic factors for invasive aspergillosis (joint effort with the EORTC Leukemia Group, the Infection Group of the MASCC, and the EBMT-IDWP).

Clinical validation of the standard for Aspergillus PCR to screen for invasive aspergillosis (joint effort with EORTC Leukemia Group, the ISHAM-EAPCRI, and EBMT-IDWP).

Prospective study to explore the value of biomarkers of separately and in combination for the early detection of invasive fungal infection.

Epidemiological studies

European register of invasive aspergillosis using ECMM-internet register.

Education and training

Training courses and seminars using the full potential digital communications of WEB casting, Web Events, and WEBinars.

Open positions for fellowships

One fellowship leading to a PhD concerns the prospective epidemiology and diagnosis of IFDs.

A second fellowship on the prospective epidemiology and clinical impact of bacteremia due to resistant bacteria is envisaged.

www.eortc.org/research-groups/infectious-diseases-group

Structure of the Group

Chair	**J.-P. Marie, Paris (FR)**
Secretary	**F. Baron, Liège (BE)**
Treasurer	**P. Muus, Nijmegen (NL)**

The aim of the EORTC Leukemia Group (LG) is to organize, conduct, coordinate, and stimulate trials for patients with myeloid or lymphoid leukemias and myelodysplastic syndromes (MDS). The LG includes 52 qualified hematology centers located in 13 different European countries. Biological investigations are coordinated by subcommittees of experts on cytogenetics, molecular biology, cytology, and immunology. The LG conducts meetings on a bi-annual basis.

Recent Achievements

Acute Myeloid Leukemia (AML) in "young" (< 60 years) patients

Final results of the AML-10 phase III EORTC-GIMEMA 06931 trial comparing Daunorubicin *versus* mitoxantrone *versus* idarubicin as induction and consolidation chemotherapy were published (Mandelli et al. J Clin Oncol 2009;27:1-8).

The AML-12 EORTC-GIMEMA 06991 trial included randomization at diagnosis for remission induction using high-dose ARA-C compared to the "best" remission induction schedule of the previous AML-10 trial. A total of 2112 patients were registered (the randomization was completed in January 2008). A second randomization evaluated the role of maintenance therapy with low-dose subcutaneous interleukin-2 *versus* no further treatment; a total of 550 patients were randomized for this second step (randomization closed in June 2008). Younger patients (< 45-55 years) with an HLA identical family donor were scheduled for allogeneic transplantation. The "top results" of the final analysis were available mid-2011 and led to an oral presentation and a poster at the American Society of Hematology (ASH) Meeting (December 2011), and several manuscripts are in preparation. The two main messages of this trial is the benefit of high dose ARA-C during induction for patients under 46 years of age in terms of response to induction and overall survival, and the absence of efficacy of IL2 alone to prevent relapse.

An EORTC/GIMEMA network of laboratories in The Netherlands, Belgium, and Italy and coordinated by Dr Joop Jansen (EORTC) and Dr Francesco LoCoco (GIMEMA) monitored minimal residual disease by molecular techniques to identify its prognostic importance.

A phase I EORTC-GIMEMA 0606 trial testing the addition of low dose clofarabine to the idarubicin-ARA-C combination was completed and has been presented at the last ASH meeting. The phase II trial is now open in a limited number of large centers.

The LG also participated to a large intergroup study, the EORTC 06071 trial, led by CALGB for young patients with flt3-positive AML. This study aims to determine if the addition of midostaurin to daunorubicin/cytarabine induction followed by high-dose cytarabine consolidation and continuation therapy improves the outcome of these patients. The challenge of this trial was to obtain molecular data on fresh blasts within three working days, a delay compatible with the beginning of induction

treatment of AML. The NOCI center of Nimegen (J Jansen) was able to respond very quickly to this challenge. The study recruitment was reached in October 2011.

Acute Myeloid Leukemia in elderly (> 60 years) patients

In elderly patients (> 60 years) with AML, the LG completed the EORTC 06012 AML-17 intergroup trial with GIMEMA. In 61-75 year old patients in good physical condition, this trial assessed the anti-leukemic activity of a sequential treatment with Mylotarg (anti-CD33+calicheamycin) followed by "standard" chemotherapy with mitoxantrone, Ara-C and Etoposide as a front-line therapy in previously untreated AML. This regimen is compared to "standard" chemotherapy. The target sample size for this study was reached and the accrual was closed in August 2007 with a total of 473 patients randomized. Final analysis of the data was performed early this year, and the results were presented orally at the last European Hematology Association meeting (June 2012). Given sequentially, Mylotarg did not increase remission rate or survival.

Acute Myeloid Leukemia in "frail" (> 75 or 61-75years with comorbidity) patients

The EORTC-GIMEMA 06031AML-19 trial was designed for "frail" patients (> 75 or 61-75 years with co-morbidity) who are usually not treated with intensive chemotherapy. The aim of this phase II-III trial is to compare low doses of Mylotarg *versus* palliative care. During the phase II part, activity of two different schedules of low dose Mylotarg have been assessed (84 patients have been entered in the phase II), and results were published (Amadori et al, *Br J Haematol* 2010;**149**(3):376-382). The phase III part has been open to accrual since September 2007, and patients are being randomized between supportive care and the "best" low dose Mylotarg schedule following analysis of the phase II results. The trial will be completed before the end of 2012. Discussions are ongoing with Pfizer on the possibility of upgrading this to a registration trial after the rejection by the US Food and Drug Administration of Mylotarg in AML patients treated with Mylotarg and chemotherapy.

Myelodysplastic Syndromes

The randomized EORTC 06011 phase III trial of the LG and the German MDS Group assessing the value of decitabine *versus* best supportive care in high risk MDS patients >60 years old, recruited 233 patients in 46 centers, and the final results have been published (*J Clin Oncol* 2011;**29**(15)**:**1987-1996).

Acute Lymphoblastic Leukemia (ALL)

A new ALL first line therapy (with stratification: 18-40 years, 41-70 years) with a randomization for -/+ clofarabine *i.v.* during induction and intensification using a pediatric-like regimen in "young" ALL has been activated by HOVON (HOVON 100 ALL) and EORTC (the EORTC 06083 trial). The primary endpoint will be event free survival (EFS), and the secondary endpoint will be molecular residual disease.

Supportive Care: Antifungal therapy

Our group developed with the Infectious task force the 65091-06093 trial: "Empirical *versus* pre-emptive (diagnostic-driven) antifungal therapy of patients treated for haematological malignancies or receiving an allogeneic stem cell transplant. A therapeutic open label phase III strategy study of the EORTC Infectious Diseases and Leukemia Groups". This trial is particularly well adapted for patients with long-lasting neutropenia (as in AML and MDS patients), and asks the crucial question of empirical *versus* pre-emptive anti-fungal treatment in case of persisting fever. A vast program of translational research is linked to this trial (validation of pre-emptive tools).

Projects and Strategies for the future

Platforms for elderly AML

The LG together with the EORTC Headquarters team is developing a strategic platform for elderly AML with participation of the EORTC Cancer in the Elderly Task Force. In June 2012 it was endorsed by the EORTC Board. The main aim of this platform is to create a database of patient characteristics, cytogenetic and biological features, standardized fitness scoring, treatments received and clinical outcomes of a large series of elderly patients with a view to perform a large joint prospective analysis of clinical and biological data from elderly patients with AML. The platform will also include strategies for supportive care and a registry to explore the feasibility of reduced intensity conditioning for bone marrow transplant in subsets of the elderly population.

Collaboration with other groups

The LG has a very close relationship with the Italian GIMEMA group, and many clinical studies are joint studies of these two groups. This combination is very advantageous for both groups, since this intergroup is the largest group for leukemia research in the world. Our group also has a fruitful collaboration with the German MDS Study Group and, more recently, with the Dutch HOVON group for adult ALL.

The LG is a member of the AML Collaborative Group, which comprises all co-operative groups (MRC, HOVON, ECOG, etc.) performing meta-analyses in AML.

Several LG centers are active participants in the European Leukemia Network, financed by the European Commission (Network of Excellence) since 2004, and participate actively in the MDS, ALL, and SCT working groups. Many members of the LG are also participating in European Cooperative Group for Blood and Marrow Transplantation (EBMT) activities. The EORTC statistician is involved in projects (guidelines, courses) of the EBMT Statistical Subcommittee.

The group is developing a fruitful collaboration with the CELG (Central Eastern European Leukemia Group) network consisting of centers from 11 countries from Central and Eastern Europe. We propose to set together standards for care for AML/MDS. These standards will included minimum diagnosis settings (cytology, immunophenotype, cytogenetic and selected molecular biology) and reference treatment (for young (<60 years) and older AML/MDS patients), according to our large experience with previous trials in young and elderly patients. This "elderly" platform (described earlier) will be used for short "pick the winner" trials, where these "reference" treatments will be compared by randomization to an experimental arm, by addition/substitution of one drug, in phase II studies.

Translational Research

Cytogenetics and molecular biology are now mandatory for all patients with AML or MDS. A broad molecular analysis is linked to each clinical trial permitting identification of new prognostic molecular markers, and the development of RNA, DNA and frozen cell banks allows for better adherence to these programs. Systematic evaluation of TCR or IgH gene rearrangements is planned in the next EORTC/HOVON adult ALL trial.

The LG TET2 project (Prognostic impact of mutations and correlation with known genetic defects of the novel oncogene/tumor suppressor TET2 in *de novo* acute myeloid leukemia patients: translational research study of the EORTC phase III 06991 trial") which was presented by S Langemeijer and J

Jansen (Nijmegen, The Netherlands) at the 2009 EGAM meeting and granted by the EORTC Board, was performed on the samples from four EORTC centers as well as approximately 20 GIMEMA centers.

AML/MDS central biobanking

Frozen leukemia cells (blood and bone marrow) are routinely stored in both EORTC and GIMEMA centers for on-going and further translational research. After the experience of TET2 project, the development of a centralized EORTC leukemia Bank in the NOCI Center of Nijmegen is under development.

Quality Assurance

Independent review of cytology, cytogenetics, molecular biology, and immunology by four subcommittees and occasional site visits to participating centers have led to improvement in the quality of LG studies.

www.eortc.org/research-groups/leukemia-group

Structure of the Group

Chair	**M. O'Brien, Sutton (UK)**
Secretary	**V. Surmont, Gent (BE)**
Treasurer	**B. Biesma, 'S Hertogenbosch (NL)**

Steering Committee Members

Sub-chair Surgery	P. Van Schil, Antwerp (BE)
Sub-chair Pathology	K. Kerr, Aberdeen (UK)
Sub-chair Oncology	D. Fennell, Leicester (UK)
Sub-chair Radiotherapy	C. Favre-Finn, Manchester (UK)
Sub-chair Quality Assurance	R. Gafar, Cairo (EG)
Sub-chair Radiology	C. Fink, Mannheim (DE)
Young Oncologists	R. Dziadziuszko, Gdansk (PL) L. Greillier, Marseille (FR)

Recent Achievements

In 2010, two trials were closed to patient entry: EORTC trial 08052 was closed after attaining full accrual, and EORTC trial 08061 was closed due to poor accrual. The final analysis report was completed for EORTC trial 08062. A total of 74 patients were entered in EORTC Lung Cancer Group (LCG) trials in 2010.

In 2011, one trial in non-small cell lung cancer (NSCLC), EORTC trial 08092, was open to patient recruitment. A total of 78 patients were entered in LCG trials in 2011.

During first half of 2012, the final analysis report was completed for EORTC trial 08052 and a non investigational trial in NSCLC was developed.

Non-Small Cell Lung Cancer

- **EORTC trial 08021**: A randomized phase III study of follow-up with or without adjuvant gefitinib (Iressa) following chemotherapy in patients with advanced NSCLC. This trial closed in 2008 due to slow accrual. The slow accrual was triggered by the negative results in SWOG 0023 and ISEL (IRESSA Survival Evaluation in Lung cancer) studies. Iressa has recently been licensed for use in patients with epidermal growth factor receptor (EGFR) mutations. Abstracts concerning this trial were presented at ASCO 2010 and at ESMO 2010 as poster discussions.
- **EORTC trial 22055 -08053**: Lung Adjuvant Radiotherapy Trial (Lung ART) evaluating the role of postoperative conformal radiotherapy after complete resection of NSCLC with N2 mediastinal involvement. This trial was closed prior to recruiting its first patient. Because of the relevance of the question addressed by this protocol, its feasibility was reevaluated and now several sites will receive the initiation package.

- **EORTC trial 08092 (MAPPING)**: Double blind randomized phase III study of maintenance Pazopanib *versus* placebo in NSCLC patients non-progressive after first line chemotherapy. This study has opened and is recruiting.
- **EORTC trial 75082-08086**: Randomized phase II trial of abraxane *versus* navelbine for patients aged 70 or older with NSCLC. This study is no longer under development in collaboration with the EORTC Cancer in the Elderly Task Force in view of recent results presented at ASCO 2010.

Small Cell Lung Cancer

- **EORTC trial 22074-08072 CONVERT**: 2-arm randomized, controlled, phase III trial of concurrent chemo-radiotherapy comparing twice-daily and once-daily radiotherapy schedules in patients with limited stage small cell lung cancer (SCLC) and good performance status. This trial has started and is being conducted together with the EORTC Radiation Oncology Group and the United Kingdom Medical Research Council. It is the only phase III trial in LS-SCLC in Europe, and is considered to be of great importance for patients with limited stage SCLC. It is designed to answer the question of dosing and timing of radiation to the chest. Patients are randomized to receive twice daily radiation with concurrent chemotherapy *versus* four courses of chemotherapy followed by high dose radiation of 66 Gy.
- **EORTC trial 08062**: Randomized phase II study of amrubicin as single agent or in combination with cisplatin versus etoposide/cisplatin as first-line treatment in patients with extensive stage SCLC. The activity of amrubicin single agent or amrubicin with cisplatin versus the standard treatment cisplatin/etoposide was investigated. Amrubicin exhibited comparable response rate as a single agent (61%) to cisplatin/etoposide (63%) and a promising response of 77% in combination with cisplatin (Eur J Cancer 2011;47(15):2322-2330).

Mesothelioma

- **EORTC trial 08031**: A phase II feasibility trial of induction chemotherapy followed by extra pleural pneumonectomy and postoperative radiotherapy in patients with malignant pleural mesothelioma. The study investigated the feasibility of combining induction chemotherapy, extra pleural pneumonectomy and hemi-thoracic irradiation in patients with early stage mesothelioma. The endpoint is the number of patients alive and without significant toxicity or disease at 90 days after the last treatment, and the data suggest that this is only possible in <50% of patients (Eur Respir J 2010; 36(6):1362-1369). Translational research related to this study is ongoing.
- **EORTC trial 08052**: A phase II study of bortezomib (Velcade) with cisplatin as first-line treatment of malignant mesothelioma. This trial is assessing the effect of bortezomib with cisplatin in patients with inoperable malignant mesothelioma. The primary endpoint is progression free survival at 18 weeks; secondary endpoints are overall survival and toxicity. A translational research component of this study is linked to **EORTC trial 08031**. The study has completed recruitment and was presented at ASCO 2012 as a poster. Publication is expected end of 2012.

Projects and strategies for the coming years

The LCG worked closely in 2011 with EORTC Headquarters to develop a strategy for the coming years focusing initially on NSCLC. Currently several new projects are under discussion in the LCG, among them four concern NSCLC. The LCG strategy meeting held in October 2011 placed emphasis on early disease and pre-surgical settings. The group has dedicated members with strong expertise in mesothelioma, translational research, as well as nuclear medicine.

Translational Research

Translational research is an important component of our studies, and data collection and tissue storage for future use are considered very important. Our pathology Sub-chair and Young Oncologist have been active in developing protocols for tissue transport and research. A customized secure web-based portal has been developed for virtual tissue archiving of samples from **EORTC trial 08031** and will be used as a platform for centralized review of biomarkers in future clinical trials. Tissue microarrays have been developed in collaboration with LCG centers in Aberdeen and Belfast enabling multiple biomarker evaluation. For tissue collected in **EORTC trial 08092 MAPPING**, the medical oncology sub-chair, Dr. D. Fennell, will coordinate tissue banking which will enable rapid tissue processing, nucleic acid extraction, and the ability to conduct an array of molecular tests including expression or micro RNA array analysis, DNA copy number analysis, or quantitative PCR. This should support future development of personalized therapies based on tumor genetic profiles. The LCG will continue to invest in these studies.

Collaboration with other Groups

The LCG has ongoing collaborations with the EORTC Imaging Group and plans future collaboration with the EORTC Pathobiology and Head and Neck Cancer Groups.

EORTC LCG participates in the International Rare Cancers Initiative and collaborates with the Thymoma group for a study in patients with stage III thymoma.

www.eortc.org/research-groups/lung-cancer-group

Structure of the Group

Chair	**R.W.M. van der Maazen, Nijmegen (NL)**
Secretary	**P. Meijnders, Antwerp (BE)**
Treasurer	**E. Lugtenburg, Rotterdam (NL)**
Executive Committee	R.W.M. van der Maazen, Nijmegen (NL) P. Meijnders, Antwerp (BE) P. Lugtenburg, Rotterdam (NL) B.M.P. Aleman, Amsterdam (NL) J.C. Kluin-Nelemans, Groningen (NL) J.M.M. Raemaekers, Nijmegen (NL) M. Hutchings, Copenhagen (DK) M. van der Kaaij, Amsterdam (NL) E. Shash, Brussels (BE) C. Fortpied, Brussels (BE)

In the past, the EORTC Lymphoma Group has conducted trials in the area of malignant lymphomas, both Hodgkin and non-Hodgkin. Mainly due to national initiatives, the LYMG has been forced to focus only on the treatment of patients with Hodgkin Lymphoma (HL).

HL is a rare disease. When treated correctly a high cure rate can be achieved. However, late toxicity (second cancers, cardiovascular diseases, fatigue) has become a major concern. New trial initiatives are aimed at reducing both acute and late toxicity while maintaining high cure rates.

The scientific strategy of the LYMG is explored at LYMG Scientific Steering Committee meetings chaired by M. Hutchings; ongoing studies are evaluated and new initiatives are discussed. Our goal is to achieve a better basis for personalized treatment of newly diagnosed patients with HL that gives the best chances for survival with minimal toxicity taking into account the patient's prognosis, individual characteristics, and personal preferences.

Recent Achievements

- **EORTC trial 20012** (P. Carde, N. Mounier): an Intergroup (EORTC, Lymphoma Study Association (LYSA), Australasian Lymphoma Leukemia Group (ALLG), National Cancer Research Institute Lymphoma Group (NCRI LYG), Grup per l'Estudi dels Limfomes de Catalunya i Balears (GELCAB), National Cancer Institute of Canada (NCIC), and Nordic Lymphoma Group (NLG)) phase III randomized trial comparing BEACOPP (cyclophos-phamide, doxorubicin, etoposide, procarbazine, prednisone, bleomycin, vincristine; four cycles escalated + four cycles baseline) versus ABVD (doxorubicin, bleomycin, vinblastin, dacarbazine; eight cycles) in high risk stage III & IV HL having reached complete remission after six cycles. The required number of patients was reached in January 2010. The final results were presented at ASCO 2012 (oral), and this was selected to be included in the Best of ASCO program.

- **EORTC 20051- H10 trial** (J.M.M. Raemaekers): an Intergroup (EORTC, LYSA, and the Italian Lymphoma Foundation (FIL)) phase III randomized trial on early 18F fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) scan guided treatment adaptation versus standard combined modality treatment in patients with supra-diaphragmatic stage I/II HL.

An interim analysis of efficacy was performed and reviewed in June 2010 by the EORTC Independent Data Monitoring Committee. The primary objective of the study (can radiotherapy be avoided in early PET-negative patients?) was unlikely to be met, so this part of the study was closed. The study remained open to accrual until June 2011 for the secondary objective (Is intensified treatment superior to standard treatment in early PET positive patients?). Two additional questions based on the PET scan after two cycles of adriamycin (doxorubicin), bleomycin, vinblastine, and dacarbazine (ABVD) are being investigated, namely a comparison of visual and quantitative assessment of the PET scan and the incidence of positive PET scan in relation to the presence or absence of bulky mediastinal disease.

- **EORTC 20982- H9 trial** (J. Thomas and C. Fermé; EORTC and LYSA). Two articles, "Comparison of 36 Gy, 20 Gy or no involved field-radiotherapy after six cycles of EBVP chemotherapy in early-stage Hodgkin's Lymphoma with a favorable prognosis: Results of the EORTC–GELA H9-F intergroup randomized trial" and "Combined ABVD or BEACOPP and involved-field radiotherapy in early-stage Hodgkin's Lymphoma with an unfavorable prognosis: Results of the EORTC–GELA H9-U intergroup randomized trial", have been finalized and a publication is in preparation.
- **Long-term survivorship** in European patients treated for HL (M. Henry-Amar): The LYMG has included more than 6000 patients in EORTC/GELA HL trials over the last 45 years. The purpose of this cross-sectional study is to evaluate the consequences of the disease and its treatment on social, professional and private life as well as detection of late side effects in survivors enrolled during this period of time. In the first part of the project which was completed in October 2010, 3604 living patients received a Life Situation Questionnaire which included questions in six categories: general, parenthood, education/work, health, social life, and support. The results will provide extensive information on the quality of life of these long-term survivors. The second part of this project will be to perform a clinical update evaluating the long term physical adverse effect of treatment and outcome. For this purpose, a medical questionnaire will be sent to all participating sites. Part of this project is financed by the Lance Armstrong Foundation.

Future strategies

Advanced stage Hodgkin's Lymphoma

- **The EORTC 20101-H11 trial** (M. Hutchings) was endorsed by the EORTC Executive Committee in May 2010. The main objective of this trial is to show that ABVD based response adapted therapy for advanced stage HL with treatment intensification in case of a positive FDG-PET after one cycle of ABVD has non-inferior efficacy compared with the intensive BEACOPP regimen (now considered by many as standard treatment). The aim of this strategy is to limit the intensified treatment and its toxicity to those patients who really need it to be cured.

Part of the H11 trial will focus on the prospective correlation of thymus and activation regulated cytokine (TARC) expression. TARC can be detected in the serum of patients with untreated HL, and the level depends on the disease activity. Its value as an early predictor of refractory or recurrent

disease will be monitored (G. van Imhoff). A new cardiac ide study aiming to assess long term related cardiac toxicities has been added to the protocol.

In a limited amount of patients, radiotherapy will be part of the treatment. Central prospective quality assurance of the radiation treatment will be performed in close collaboration with the radiotherapy group (B. Aleman).

Relapsed or refractory Hodgkin's Lymphoma

Preparations are ongoing for a new study for patients with relapsed or refractory HL (HDR3) that will focus on the induction chemotherapy schedule (adding the mTOR inhibitor Everolimus, HDR3i) and the possible role of maintenance therapy after autologous stem cell transplantation with an HDAC inhibitor (Panobinostat, HDR3m). The maintenance part is a Novartis driven trial for participation with individual EORTC centers (J. Baars and I. Aurer).

Fatigue project

A nested case control study is currently under preparation within the population which participated in the cross-sectional long term survivorship study (see above). This study will focus on the assessment of unexplained (i.e., non-medical) persistent fatigue and identification of risk factors. Biological mechanisms to understand this persistent fatigue will also be investigated as an exploratory endpoint (M. Henry-Amar).

www.eortc.org/research-groups/lymphoma-group

Structure of the Group

Chair	**A. Testori, Milan (IT)**
Secretary	**C. Robert, Paris (FR)**
Treasurer	**G. Ghanem, Brussels (BE)**
Chair elect	D. Schadendorf, Essen (DE)

The Melanoma Group (MG) currently has seven committees engaged in the management of cutaneous and ocular melanoma, development of new treatment strategies, and conducting epidemiological, genetic, and pathological research in melanoma. A Translational Research Committee serves to foster transversal interaction between the Pathology, Translational Research, and Epidemiology Committees.

Chair Adjuvant Therapy Committee	A.M.M. Eggermont, Paris (FR)
Chair Epidemiology Committee	E. de Vries Rotterdam (NL)
Chair Ocular Melanoma Committee	S. Leyvraz, Lausanne (CH)
Chair Pathology	M. Cook, Guildford (UK)
Chair Stage IV Melanoma Committee	U. Keilholz, Berlin (DE)
Chair Surgery Committee	A. Testori, Milan (IT)
Chair Translational Research Committee	D. Schadendorf, Essen (DE) L. van Kempen, Montreal (CA)
Chair Early Staging Committee	S. Puig, Barcelona (ES)
Young Oncologists / Scientists	A. Van Akkooi, Rotterdam (NL) H. Franks, Nottingham (UK)
EORTC Melanoma Group Fellow	M. Suppa, Brusselks (BE) *(2012-2013)*

Recent Achievements

Completed trials

STAGE IV Melanoma

- **EORTC trial 18032**: Extended schedule, escalated dose Temozolomide (TMZ) versus Dacarbazine (DTIC) in Stage IV metastatic melanoma: a randomized phase III study. *Study Coordinator: P. Patel*. This trial, one of the largest ever in stage IV melanoma, evaluated the use of an extended schedule and escalated dose TMZ in stage IV melanoma. The trial recruited 859 patients over four years. There was no significant difference in overall survival (OS): median survival was 0.76 (TMZ) and 0.78 years (DTIC); hazard ratio (HR) 0.99. Median progression free survival (PFS) was equal in both arms: 0.19 versus 0.18 months. Overall response rate (ORR) was 14.5 versus 9.8 % (TMZ versus DTIC). The main toxicities were hematological and were more pronounced in the TMZ arm (41.3% versus 23.6% grade 3 / 4). (Eur J Cancer 2011;47(10):1476-1483).
- **EORTC trial 16032-18031**: Randomized, open phase II study of immunization with the recombinant MAGE-3 protein combined with adjuvant AS02B or AS15 in patients with unresectable and progressive metastatic cutaneous melanoma. *Study Coordinator: W. Kruit*. This trial evaluated the

activity and toxicity of two adjuvants, AS02B and AS15, in combination with MAGE-3 protein in the treatment of metastatic cutaneous melanoma. In the AS15 arm (N=36), three patients reached complete response (CR) and one patient reached partial response (PR). In the AS02B arm (N=36), one PR was reported. In addition, eight (AS15 group) versus five (AS02B arm) patients received vaccinations during more than 16 weeks after randomization. Anti-MAGE-3 antibody titers were higher in the AS15 arm than in the AS02B arm. A manuscript has been submitted for publication.

- **EORTC trial 18021**: Intravenous (IV) versus hepatic intra-arterial (HIA) fotemustine chemotherapy in patients with liver metastases from uveal melanoma: a randomized phase III study. *Study Coordinator: S. Leyvraz*. This trial was activated in 2004 and targeted 262 patients. Between February 2005 and February 2011, 171 patients were randomized (HIA: 86, IV: 85). Due to poor accrual, an interim analysis was performed after 134 deaths in order to test futility (power=79%). In the HIA arm 20 (23%) patients never started treatment mainly due to catheter problems; in the IV arm 2 patients never started treatment. In those who started the randomized treatment, leucopenia > grade 3 was 18% and thrombopenia > grade 3 was 21% in the HIA arm compared to 33% and 42% in the IV arm, respectively. Non-hematological > grade 3 toxicities were minimal and consisted mainly in gastrointestinal toxicity and catheter complications. In May 2011, the hazard ratio for OS, HR = 1.097, was greater than the critical value, HR = 0.87. The Independent Data Monitoring Committee recommended stopping accrual for futility. In January 2012, treatment comparison provided similar results. Even if HIA fotemustine administration could not start or was stopped early due to catheter placement problems in 28% of patients, it led to a higher ORR (12% versus 2%) and longer PFS (HR=0.62; 6-month rate 41% versus 27%; 1-year rate: 19% versus 8%) compared to IV administration. HIA did not translate into an improvement in OS (median ~ 13.5 months). HIA should remain an experimental therapy. Results were presented at ASCO 2012 and a manuscript is currently in preparation.

STAGE III Melanoma

- **EORTC trial 18952**: Randomized phase III trial. Post-operative adjuvant Interferon-alpha 2b (IFN) treatment after resection of thick primary melanoma and/or regional lymph node metastases "intermediate-high dose" versus "intermediate-low dose" Interferon-alpha versus observation. The first results were published (Lancet 2005;366:1189-1196). The study is in long term follow up with updated analyses foreseen in Q3 2012. The most recent publication related to the study reported that compared to baseline values, ferritin levels at end of induction were significantly higher in IFN treated patients (N=96) compared with untreated patients (N=21) (mean: 2.88 versus 0.75; P=0.0003) and at six months (mean: 3.18 versus 1.02; P=0.009), respectively **(**Melanoma Res 2011;21:344-351). In the IFN arm, higher ferritin ratios at the end of induction and at six months were not associated with improved outcome. Concerning C-reactive proteins (CRP) ratios, no differences were observed between the treatment groups, nor was an association with distant metastasis free survival (DMFS) observed. Administration of IFN in melanoma patients induced increase in ferritin levels but not in CRP levels. Ferritin and CRP ratios have no prognostic value regarding DMFS.
- **EORTC trial 18991**: Randomized phase III: Adjuvant PEG Intron (five years) versus observation after regional lymph node dissection in American Joint Committee on Cancer (AJCC) Stage III (TxN1M0) melanoma patients: a multicenter randomized phase III trial. *Study Coordinator: A. M. M. Eggermont.*This trial investigated the effect of long-term therapy with the long-acting pegylated

interferon alpha 2b (PEG-Intron) versus observation on relapse-free survival (RFS), DMFS and OS, in high risk melanoma patients after full lymph node dissection of positive regional lymph nodes. Stratification factors were microscopic (N1) versus macroscopic (N2) nodal involvement, number of positive nodes, ulceration and tumor thickness, sex, and center. The study accrued 1256 patients. The median length of treatment with PEG-Intron was 12 months. At 3.8 years median follow-up, 328 recurrence events had occurred in the PEG-Intron group compared with 368 in the observation group (HR=0.82, 95% CI 0.71–0.96; P=0.01); the 4-year RFS rate was 45.6% in the PEG-Intron group and 38.9% in the observation group. There was no difference in OS between the groups (Lancet 2008;372(9633):117-126). The United States Food and Drug Administration (FDA) approved this drug on 25 March 2012 based on this trial for this indication. At 7.6 years median follow-up, 384 recurrences or deaths had occurred with PEG-Intron versus 406 in the observation group (HR, 0.87; 95% CI 0.76-1.00; P=.055); 7-year RFS rate was 39.1% versus 34.6%. There was no difference in OS (P = .57). In stage III-N1 ulcerated melanoma, RFS (HR=0.72; P = .06), DMFS (HR=0.65; P = .02), and OS (HR=0.59; P = .006) were prolonged with PEG-Intron. PEG-Intron was discontinued for toxicity in 37% of patients. Adjuvant PEG-Intron for stage III melanoma had a positive impact on RFS, which was marginally significant and slightly diminished versus the benefit seen at prior follow-up (median, 3.8 years). No significant increase in DMFS or OS was noted in the overall population. Patients with ulcerated melanoma and lower disease burden had the greatest benefit. A manuscript has been submitted for publication.

Meta-analysis

As ulcerated (Ulc) melanomas have a worse prognosis than non-ulcerated (N-Ulc) melanomas due to differences in their biology, the outcome after adjuvant IFN therapy in the above mentioned phase III trials (**EORTC trials 18952 and 18991**) was analyzed. The results show a significant benefit of adjuvant IFN versus observation only in patients with ulcerated primaries (Eur J Cancer 2012;48(2):218-225). In the Ulc group (N=849) the treatment effect was much greater than in N-Ulc group for RFS (Test For Interaction: P=0.02), DMFS (P<0.001), and OS (P<0.001). The greatest impact occurred in patients with Ulc and stages IIB/III-N1 with estimated HR for RFS, DMFS, and OS of 0.69 (P = 0.003), 0.59 (P < 0.0001) and 0.58 (P < 0.0001), respectively. This hypothesis will now be tested in **EORTC trial 18081** (see below).

STAGE II Melanoma

EORTC trial 18961: Post-operative adjuvant ganglioside GM2-KLH/QS21 vaccination treatment after resection of high risk primary melanoma (> 1.5 mm) (TNM: T3-4N0M0: stage II). A 2-arm multi-center randomized phase III trial. *Study Coordinator: A. M. M. Eggermont.* This study reached the required number of patients and was closed to patient entry in December 2005, and an interim analysis took place in 2007. For the primary endpoint DFS, the criteria for stopping for futility were met. The IDMC thus recommended that the trial be stopped as it was highly unlikely that a benefit of the vaccine would be observed. The recommendation was immediately endorsed by the MG Executive Committee and the treatment with the vaccine was stopped in the patients still receiving treatment. Thereafter, patients continue to be followed for RFS, DMFS and OS endpoints. At a median follow-up of 4.2 years, the number of events for the final analysis was reached. Final results were presented at the ASCO 2010 meeting (J Clin Oncol 2010;28:15suppl, abstr 8505). A manuscript is in preparation.

Ongoing Studies

- **EORTC trial 18071**: Adjuvant Immunotherapy with anti-CTLA-4 Monoclonal Antibody (ipilimumab) versus Placebo after complete Resection of high-risk Stage III Melanoma: A randomized, double-blind Phase III Trial. *Study Coordinator: A. Eggermont.* The primary objective of this study is to prospectively assess whether post-operative adjuvant therapy with ipilimumab improves RFS, OS and DMFS as compared to placebo in high-risk patients with complete resection of Stage IIIA (< 1mm metastasis), IIIB and IIIC (no in-transit metastasis) melanoma. The study was closed to recruitment in June 2011 with 951 patients randomized. Final analysis is foreseen in 2013.
- **EORTC trial 18081**: Adjuvant Pegylated-Interferon-alpha2b for 2 years versus Observation in patients with an ulcerated primary cutaneous melanoma (T1b-T4bN0M0): a randomized phase III trial of the Melanoma Group. *Study Coordinator: A. Testori. Study Chair: A. Eggermont.* In order to explore the biological significance of melanoma ulceration on patient outcome and response to treatment, this study incorporates an integrated prospective translation research program, aiming to prospectively collect biological material (whole blood, plasma, serum and tissue) for translational research projects from patients who have consented to take part in this research. Projects may include but are not restricted to:
    - assess correlation between single-nucleotide polymorphisms to PEG-Intron sensitivity;
    - analyze the association of potential biomarkers present in the subject's blood, serum/plasma and/or tumor tissue with clinical benefit post-treatment in the form of RFS, DMFS and OS in order to identify candidate markers predictive of response to PEG-Intron;
    - determine the prognostic value of biomarkers on human plasma/serum and tissue in correlation to other validated prognostic factors and to the clinical course of melanoma patients / CRP, neutrophils, circulating micro-RNAs, vitamin D level, and Th1 response amongst others.

The protocol, approved by the EORTC Protocol Review Committee, has been approved by the FDA through a Special Protocol Assessment. First patients in are foreseen in August 2012.

Translational Research

There is an evidence level 2 that sentinel node (SN) is the best staging procedure in cutaneous melanoma. Patients with negative SN constitute a homogeneous group of patients with good prognosis (90-95 % 5-year survival rate). Therefore, only patients staged by SN procedure will be included in adjuvant trials. This SN micro-staging should systematically follow the protocol established by the MG, as differences in pathology protocols can lead to variations in the SN reliability. In the meantime, there is a need to better understand the individual susceptibility to melanoma relapse: 50% of patients with a micro-metastatic SN will die from their disease. There is a need to better understand at the N1 stage which factors influence the risk for relapse. A constitutional genetics study has been launched to address this issue.

It has been demonstrated by the Erasmus group that SNs with micro-metastases below 0.1 mm in diameter are associated with virtually the same prognosis as negative SNs (Ann Oncol 2006;17:1578-1585, Br J Surg 2007;94:1293-1299, Ann Surg 2008;248:949-955, and J Clin Oncol 2011;29(16):2206). Whether SNs with small micro-metastases should lead to completion lymph node dissection (CLND) or not will be addressed by a controlled study currently in preparation. The MG is conducting a registration study examining the outcome of conservative management in low

risk minimal microscopic SN positive patients (the EORTC 1208 MINUTUB trial). The MG has also investigated whether the ultrasound guided fine needle aspiration cytology (FNAC) prior to surgical SN staging is a cost-effective approach (Melanoma Res 2010;20(4):357-359).

Projects and strategies for coming years

The future strategy of the MG will focus on:

- Hypothesis driven Translation Research;
- Launching phase II studies in Stage IV with focus on rare diseases in close collaboration with the EORTC Early Project Optimization Department (EPOD)
- Identify biomarker discovery platforms within the MG in close collaboration with the EORTC Pathobiology Group

One new study is being planned:

- **EORTC trial 18091**: A Phase I/II Open Label Multicenter Study of ONTAK® as Treatment for advanced melanoma (stage IIIc and stage IVM1a): a trial of the EORTC Melanoma Group. The outline was approved by the EORTC Protocol Review Committee, and a full protocol is currently being written. This study will include an integrated translational research project focusing on the time-dependent effects of E7777 on T-cell infiltrate and expression of immune response related genes by both tumor and stromal cells in longitudinal excisions of multiple metastases.

Uveal melanoma is the focus of several new concepts.

Collaboration with Other Groups

CHEMORES

Members of the MG are active participants in the FP6 funded CHEMORES (Tumor Chemotherapy Resistance), an integrated project involving clinicians and scientists at 17 universities, organizations for cancer research, and research-oriented biotechnology companies in eight European countries. CHEMORES aims to improve cancer treatment by obtaining increased knowledge on mechanisms of chemotherapy resistance.

Within CHEMORES the MG is also collaborating with the AIM HIGH Study Group and the Nordic Adjuvant Group to constitute in Europe two unique centralized collections of tissues blocks. This strategy is part of an international collaborative effort initiated by Pr. Julia Newton Bishop to investigate predictive factors of interferon treatment efficacy in melanoma.

www.eortc.org/research-groups/melanoma-group

Structure of the Group

Chair	**J. Martens, Rotterdam (NL)**
Secretary	**J. Dittmer, Halle (DE)**
Treasurer	**A. Geurts, Nijmegen (NL)**
Chair-elect	R. Salgado, Antwerp (BE)

Translational research (TR) is the main mission of the EORTC Pathobiology Group (PBG), and activities of the group include biobanking, quality assurance, biomarker discovery and validation and translation of these into the clinical arena. Another important aspect of PBG activities is education, particularly the dissemination of knowledge gained from activities directed towards the development of standard operating procedures (SOPs) and policies for quality of biomarker research and biobanking.

Main activities and achievements:

Translational research

As a prominent aspect of this TR, the PBG aims to conduct research focusing on identification, validation, and working towards clinical application of cancer biomarkers associated with disease progression. Markers which provide information about diagnosis, prognosis, selection of therapy, monitoring of treatment response and side effects, assessment of individual risk, detection and characterization of micrometastases, and disseminated tumor cells (DTCs) and circulating tumor cells (CTCs) will be investigated.

Important recent biomarker discoveries:
- Prognostic genomic and proteomic signatures on triple negative breast cancers;
- Markers and proteomic/transcriptomic signatures predictive of treatment response;
- Discovery of novel markers for detection of and molecular characterization of CTCs.

Important recent biomarker validation studies:
- The Rotterdam 76-gene prognostic profile for node-negative breast cancer;
- 44-gene signature predictive of endocrine therapy response for advanced breast cancer.

Main clinically relevant achievement:
- Biomarkers uPA and PAI-1 are included in the American Society for Clinical Oncology (ASCO) guidelines as prognostic markers in breast cancer patients with node-negative disease.

Next to biomarker discovery, the PBG is actively performing functional research on discovered molecular markers related to invasion, hypoxia, stemness, and radio-, chemo- and targeted therapy resistance, e.g. uPA/PAI-1, cathepsins, TRB3, yH2AX, CA IX, TIMP-1, TOP1, etc. The PBG is also involved in drug development (e.g. inhibitors of uPA) and in the discovery of pathways abrogating therapy resistance.

Quality Assurance

Quality Assurance (QA) represents the second important task of the PBG. Over the past three decades the PBG has performed QA studies on cancer biomarkers both within and outside the EORTC which include quality assessment and QA of the reagents and test systems employed. Recently, this task was extended to QA on immuno-histochemical techniques (e.g. Her-2). An important achievement is that together with the EORTC Translational Research Unit, the PBG has developed policies for EORTC Research Groups' biobanks and laboratories and for translational research to be performed on samples from EORTC trials.

Education

As an essential part of proper TR, the third important task of the PBG is education. The PBG advises on good laboratory practice for tumor tissue or blood sample collection, storage and handling, methodologies for cancer biomarker assessment, SOPs, biochemical/cellular methodologies as well quality assessment and QA of assays used in multicenter clinical EORTC trials. The PBG is a co-founder along with US NCI and ASCO of the Annual Molecular Markers meeting and since the beginning has been very active in this meeting which has a significant emphasis on tutoring clinicians and scientists in all aspects of translational research in clinical trials.

Future Strategy

Translational research

The PBG will continue to focus its attention on biomarker discovery and multicenter validation with clinical implementation as the final aim. In addition, the PBG is available to provide advice and to stimulate biomarker research on clinical materials from EORTC clinical trials. We have initiated active collaborations on this aspect with the EORTC Radiation Oncology and Gastro-Intestinal Tract Cancer Groups as well as the Cancer in the Elderly Task Force, and expect, if mutually agreed upon, to start working actively together with other EORTC Groups in the coming years.

Quality Assurance

The PBG aims to remain the center of expertise for the EORTC with regard to quality assurance and for setting-up and disseminating SOPs. To remain strong in this field, the PBG will extend its work to QA on DNA- and RNA-based biomarkers (e.g. BRAF/KRAS/PIK3CA etc.). With the emergence of next generation technology, the PBG will extend its expertise towards this field as well, but it also intends to remain strong in QA of biochemical and immuno-histochemical markers. The PBG will also remain involved in implementing EORTC biobank policies and establishing EORTC biobanks in close collaboration with the EORTC and involved EORTC Groups. For this we foresee that collaboration with external partners, such as the European Society of Pathology with whom we are already teaming up, may be required.

Knowledge Transfer

To keep TR on a high academic level within the EORTC, the PBG will continue giving advice on biomaterial collections and TR research, and it will continue to co-organize the Annual Molecular Markers meeting.

Finally, to rejuvenate our group, we intend to actively recruit ambitious basic and TR researchers, oncologists, pathologists, and quality assurance experts in order to be able to maintain all our important activities. The PBG sees this as being essential for the biomarker driven EORTC trials of the future.

www.eortc.org/research-groups/pathobiology-group

Structure of the Group

Chair	**G.J. Peters, Amsterdam (NL)**
Secretary	**E. Raymond, Paris (FR)**
Treasurer	**A.K. Larsen, Paris (FR)**
Steering Committee	E. Chatelut, Toulouse (FR) M. Hegi, Lausanne (CH) G. Hempel, Muenster (DE) B. Leyland-Jones, Montreal (CA) R. Phillips, Bradford (UK) J. Robert, Bordeaux (FR) A. Skladanowsky, Gdansk (PL) N. Zaffaroni, Milan (IT)
Young Oncologists/Scientists	S. Faivre, Paris (FR) E. Giovannetti (NL) A. Westwell, Cardiff (UK)

The aim of the Pharmacology and Molecular Mechanisms Group (PAMM) is to stimulate research in Europe in the fields of pharmacology, pharmacokinetics, pharmacodynamics, pharmacogenetics and pharmacogenomics, and on the molecular mechanisms of anticancer drug effects and drug-related molecular pathology. In addition, the PAMM serves as a master organization for other EORTC groups such as the former Screening and Pharmacology Group (SPG), which operates as the Drug Discovery Committee (DDC).

Recent Achievements

The annual scientific winter meetings of the Group were held in February 2011 in Gdansk, Poland, and in January 2012 in Puerto de la Cruz, Tenerife, Spain. These were the first PAMM meetings in two outer regions of Europe: the former Eastern Europe and the Canary Islands. The intense interactions with the Pathobiology Group (PBG) established during the meetings in 2008 and 2009 were continued during the small EGAM in 2010 and the PBG meetings in Marseille and Rotterdam which were attended by several PAMM committee members. During the EGAM meeting in 2011 a joint symposium was organized. Several excellent informal and formal contacts have been established between PAMM and PBG committee members. One of the achievements is the contribution of the PAMM to the formulation of guidelines for biomarkers. This serves as a good basis for further interactions with the PBG.

During the DDC meeting in Tenerife the achievements of the committee were evaluated, and it was discussed how to proceed with the United States National Cancer Institute (NCI)-EORTC drug screening initiative which provided a unique evaluation platform in Europe for characterization of novel chemical entities (NCE). New chemists have been introduced to the group, who already

presented metabolism directed compounds which were evaluated in a PAMM-DDC mini-grant. Over the last decades several drugs were tested within the DDC, which not only made it to clinical trials, but were also registered. Currently, the group is involved again in EO9 (Apaziquone), for which new registration studies are planned.

Projects/Strategies for the next years

Future strategy is to link the PAMM activities more closely to the activities of the EORTC disease oriented groups. Various initiatives from both the PAMM and the disease oriented groups were reviewed during the 2011 EGAM meeting, such as jointly developed protocols. PAMM promotes young clinical investigators with interest in translational research to become members of PAMM. PAMM is in a unique position, since it provides valuable drug expertise alongside the traditional pathology directed expertise of most translational research officers of the disease oriented groups. This not only enables the performance of drug monitoring but also the evaluation of pharmacodynamic events in relation to pharmacogenomics. These analyses as well as polymorphisms have already provided the basis for tailored therapy designed to give the right drug at the right time to the right patient. Moreover, as part of PAMM's drug evaluation program, pharmacogenetic biomarkers, such as single nucleotide polymorphisms, are being and will be evaluated in relation to response prediction both for classical therapies and novel signal transduction targeted therapies. Pharmacological interactions will also be studied in collaboration with the EORTC Imaging Group. Jointly, this will provide invaluable support to clinical studies. Currently the group is developing guidelines to standardize methodology for geno – and phenotyping; naturally this approach assumes that all laboratories adhere to classical PAMM quality assurance. We aim to give a PAMM quality label to laboratories with suitable expertise.

The PAMM with its DDC forms a large reservoir of expertise for optimizing drug development and will be of invaluable help for EORTC Early Project Optimization Department (EPOD), the New Drug Advisory Committee (NDAC) as well as the Translational Research Advisory Committee (TRAC). The DDC will involve more European chemists in the group in order to include drugs targeted against resistance mutations for various tyrosine kinases. A good integration of these activities should be part of pharmacologically driven clinical studies, before drugs enter large randomized Phase III trials.

Collaborations with other Groups

Within the EORTC Network: Collaborations with the EORTC Translational Research Division (Pathobiology and Imaging Groups) and Clinical Research Division (Soft Tissue and Bone Sarcoma, Lung Cancer, Lymphoma, and Radiation Oncology, and Cancer in the Elderly Task Force) have already been established and are now being developed.

Outside the EORTC Network: Collaborations exist with the Southern Europe New Drug Organization (SENDO) and Central European Society for Anticancer Drug Research (CESAR). The PAMM is also represented in the Executive Committees of several international organizations focused on specific drugs or groups of compounds. Moreover, the DDC has close links with NCI investigators, who regularly attend the DDC meetings. Future PAMM meetings are planned in collaboration with the British Association of Cancer Research (BACR) and CESAR.

www.eortc.org/research-groups/pharmacology-molecular-mechanisms-group

Structure of the Group

Chair	**M. Groenvold, Copenhagen (DK)**
Joint Secretaries	**F. Efficace, Rome (IT)** **S. Singer, Leipzig (DE)**
Treasurer	**B. Holzner, Innsbruck (AT)**
Past chair	G. Velikova, Leeds (UK)
Module Development Committee	C. Johnson, Southampton (UK)
Translation Committee	E. Greimel, Graz (AT)
Newsletter Editor	L. van de Poll-Franse, Eindhoven (NL)
Young Investigator	F. Efficace, Rome (IT)
QoL Department Representative	A. Bottomley, Brussels (BE)

Recent achievements

The EORTC Quality of Life Group (QLG) is a multidisciplinary group including oncologists, surgeons, radiotherapists, nurses, behavioral scientists, psychometricians, and statisticians. A central activity of the QLG is the development of a modular system for assessing the health related quality of life (HRQoL) of patients with cancer for use in clinical trials and potentially in clinical practice.

This modular system includes a core questionnaire, the EORTC QLQ-C30, and more than 30 supplementary, disease-specific and/or treatment-specific questionnaire modules. The modular assessment system has been expanded to include a wider range of issues of importance to cancer patients, including their information needs, satisfaction with care, and spiritual well-being. The full, updated list of modules and their translations is available on the QLG web-site (http://groups.eortc.be/qol/). A 15-item version of the core QLQ-C30 questionnaire, the QLQ-C15PAL has been developed for use with patients in the palliative care setting. Several systematic reviews have indicated that the QLQ-C30 is the most widely used HRQoL questionnaire in randomized clinical trials.

The process of module development follows a recently updated, comprehensive manual that provides step by step procedures from early development through international field testing. Continuous peer review of the process is carried out by the Module Development Committee.

The core questionnaires and the modules are available to academic users free of charge and for a fee for commercial users from the pharmaceutical industry. The proceeds from commercial use of the questionnaires funds the QLG's research, further module development, and translations for academic use.

With the increasing globalization of clinical trials, the availability and quality of translations and cultural equivalence of any subjective measures is of paramount importance. The QLG is an international leader in developing guidelines for translations, and the QLQ-C30 has been translated into 85 languages. Translations follow rigorous, standardized, forward-backward procedures and are coordinated by the EORTC Quality of Life Department.

The QLG created the EORTC Item Bank, a searchable database that contains all items developed by the QLG including their translations. It is a very rich resource for developing questionnaires, as it ensures compatibility between different EORTC questionnaires and their translations and avoids duplication of work.

To ensure proper use of the questionnaires developed by the QLG, a user's manual is available which includes scoring instructions and syntax files for statistical software programs. The QLG has also generated a guidance manual for the conduct of clinical trial based HRQoL investigations. All of these manuals, known as "blue books", are available for download from the QLG website.

Future strategy

The QLG will maintain its focus on developing the methodology for HRQoL assessment and on applying these measures in relevant trials in close collaboration with other EORTC groups. This includes the following projects.

Computer-adaptive testing for EORTC QLQ-C30.This project is developing a dynamic, computer adaptive version of the EORTC QLQ-C30 based on modern psychometric theory and techniques. The basic idea of computer-adaptive testing (CAT) is to tailor the questionnaire to the individual respondent. Based on the responses to the preceding items it is estimated which item should be asked next to obtain maximal information. CAT has been developed for six of the 15 scales in the QLQ-30, and completion of the remaining scales is expected in 2013. The CAT is expected to improve the measurement of HRQOL in clinical trials to make it more concise, more relevant to patients, and more sensitive to differences and changes over time.

Electronic administration of the QLQ-C30. Although this has been done by individual researchers, formal development and validation of an electronic version had not been undertaken previously. Under the auspices of Dr. Holzner, a Computer based Health Evaluation System (CHES) has been developed to assess and present patient reported outcomes in both research and routine oncologic practice.

The "higher order factors" project led by Neil Aaronson, Amsterdam, The Netherlands, is intended to develop, and test the suitability of, an algorithm for computing factors which will summarize the 15 dimensional profile generated by the 30-item EORTC QLQ-C30 questionnaire into a small number of summary scales. Having a small number of HRQoL outcomes can be useful in clinical trials and might facilitate sample size calculations and avoid multiple testing in statistical analyses of HRQoL outcomes.

HRQoL of mid to long term survivors of testicular and prostate cancer from EORTC Phase III clinical trials. To better understand the physical, functional and psychosocial health problems and needs of cancer survivors, we need to supplement the currently available HRQoL measures with questionnaires specifically designed for the period of cancer survivorship. This pilot study represents a first step toward developing an HRQL-focused cancer survivorship research program within the EORTC, and is a collaboration with the EORTC Genito-Urinary Cancers Group. We focus on two important genito-urinary cancers: testicular cancer and prostate cancer.

www.eortc.org/research-groups/quality-life-group

Structure of the Group

Chair	**P. Maingon, Dijon (FR)**
Secretary	**P. Poortmans, Tilburg (NL)**
Treasurer	**S. Nuyts, Leuven (BE)**
Past Chair	V. Grégoire, Brussels (BE)
EORTC QA Committee Chair	K. Haustermans, Leuven (BE)
NOCI Liaison Officer	G. van Tienhoven, Amsterdam (NL)
QART Officers	D. Weber, Geneva (CH)
	C. Hurkmans, Eindhoven (NL)
	M. Tomsej, Charleroi (BE)
Administrator	J. Rengier-Styles, Lausanne (CH)

Steering Committee

The EORTC Radiation Oncology Group (ROG) Steering Committee is comprised of the Executive Committee, Committee Chairs (Publications, Membership, Website), Working Party Coordinators representing EORTC Disease Oriented Groups, Radiation TherapisT (RTT) Section Chair, Young Oncologist, EORTC Headquarters Team.

Radiation TherapisT (RTT) Section

Chair	F. Duclos, Lausanne (CH)
Secretary	M. Walczak, Kielce (PL)
Projects Supervisors	B. Speleers, Ghent (BE)
	M. Rossi, Amsterdam (NL)
Scientific Supervisors	H-P. van der Laan, Groningen (NL)
	M. van Os, Rotterdam (NL)

The ROG is highly productive and continually growing with almost 300 members. The ROG works in close collaboration with the majority of the EORTC disease oriented groups as well as numerous non-EORTC research groups throughout the world. The specific role of the ROG within the EORTC network lies in studying the fundamental questions related to optimal loco-regional treatments leading to maximal loco-regional control and survival rates while minimizing mutilation and side effects. Our emphasis, on the one hand, is on the design of randomized phase III trials aimed at answering a clinical question which directly contributes to the definition of new standards of care. On the other hand, our collaboration with disease oriented groups and with the EORTC Imaging and Pathobiology Groups has been reinforced. This has led to new joint initiatives such as the validation of new genomic prognostic factors for high risk prostatic carcinomas in collaboration with the Genito-Urinary Cancers Group. Quality Assurance and Translation Research are key elements in ROG projects.

Recent Achievements

- Several studies in glioma in collaboration with the EORTC Brain Tumor Group in progress:
  - The use of temsirolimus in non-methylated glioblastomas, temozolomide and radiation therapy in elderly glioblastoma patients;
  - Temozolomide and radiation therapy in anaplastic glioma;
  - Investigation of the use of temozolomide and radiation therapy in anaplastic oligodendroglioma and anaplastic mixed glioma.
  - The CENTRIC study on the use of cilengitide in combination with standard treatment for glioblastoma patients with methylated MGMT gene promoter.
  - A phase II study on atypical and malignant meningioma.
- Results of the first analysis of EORTC trial 22922/10925 evaluating the value of irradiation of the internal mammary and medial supraclavicular lymph node chain in stage I to III breast cancer are expected in the coming months.
- Analysis of EORTC trial 22991 for intermediate risk patients receiving radiation therapy with or without short term hormonal therapy will be soon performed.
- EORTC trial 26112-22112 Irradiance is under preparation with full protocol approved by the EORTC Protocol Review Committee. Quality Assurance in Radiation Therapy (QART) delivery will be managed by the QART team.
- A fruitful collaboration with the Trans-Tasman Radiation Oncology Group (TROG) within the DCIS (ductal carcinoma in situ) study and the TOPGEAR trial dedicated to preoperative treatments of esogastric carcinomas.
- A Radiation Therapy Oncology Group (RTOG) led study on locally advanced pancreas cancer.
- A project on anal cancer (PARADAC) has been completed. This meta-analysis is a joint project concerning more or less all recent anal cancer studies out of which it is hoped to plan future work in this area.
- EORTC trial 22043/30041 on postoperative radiotherapy for prostatic carcinoma is ongoing again after thoroughly modifying the protocol according to routine practices in Europe.
- The LungTec trial aiming to evaluate the role and toxicity of stereotactic radiotherapy delivered to central lung tumors has been written in close collaboration with the Imaging Group and QA platform.
- A joint protocol with the EORTC Soft Tissue and Bone Sarcoma Group is starting in the field of retroperitoneal tumors testing the role of preoperative radiotherapy. ROG is managing the QART of this trial.

Quality Assurance in Radiation Therapy

Following the implementation of the VODCA platform and the validation of the processes aiming to define QA levels and tasks in clinical trials involving high tech radiation therapy, the QART platform is up and running to provide an efficient and relevant contribution in this field. The ROG QART Team is responsible for the evaluation of submitted Facility Questionnaires (FQ) and the review of external reference dosimetry audit (ERDA) results, and provides advice and support in the writing of the QA and RT chapters together with the accompanying case report forms of new clinical trial protocols for all new studies involving RT. New procedures have been written to streamline the

development of protocols that have been endorsed by the EORTC Executive Committee. Two new papers on these topics have been published in Radiotherapy & Oncology in June 2012.

An adapted and dedicated FQ was developed for use by non-EORTC centers participating in the Merck study evaluating the use of Cilengitide in glioblastoma (CENTRIC). 208 of the 234 submitted questionnaires have been evaluated and validated by the ROG QART Team.

The QART Team is also involved in the evaluation of dummy run procedures and in the retro- and prospective review of clinical trial cases. A report of dummy run and conformity indices in the ongoing low grade glioma EORTC trial 22033-26033 describing the evaluation of the quality of radiotherapy planning was published in Radiotherapy & Oncology (Musat E. et al.).

Projects/Strategies for the coming years

Currently we have a number of new trials under development:

- PEACE 1: in collaboration with Unicancer (France). This trial will investigate the role of prostate irradiation for locally advanced tumors treated with new hormonal treatments. QART for the whole study will be managed by the EORTC QART platform.
- RTOG 09-24: collaboration with the RTOG for this trial, aiming to evaluate the impact of irradiation of the lymph nodes in intermediate risk patients. The EORTC will plan genomic testing to select patients with potentially poor prognosis and an imaging project dedicated to select new functional imaging prognostic factors.
- Protocol for N1 prostatic disease: comparison between extensive surgery and lymph node irradiation in two randomized phases II studies based on long term hormonal therapy with or without treatment of the pelvis.
- Head and Neck: a new design for a randomized phase III trial in the postoperative setting testing taxanes combined with radiation therapy was proposed.
- A joint protocol with the Danish Head and Neck Cancer Group (DAHANCA) is under discussion to promote a large randomized phase III trial validating Nimorazol in the treatment of HPV negative oropharyngeal cancers treated with intensity modulated radiation therapy.
- New rectal cancer trial: the basis of the design would be to evaluate the impact of MRI evaluation of response of neoadjuvant chemotherapy followed by combined chemoradiation prior to surgery. A strong TR program involving the Imaging and the Pathobiology Groups will be associated in collaboration with the new colorectal genomic platform.
- Early phase trials of targeted agents combined with radiation therapy: a task force group has been launched to propose a relevant infrastructure of selected centers able to test in early phase trials new targeted agents combined with radiation therapy. Contacts with companies have been initiated.

Our aim is to integrate translational research and, where applicable, functional imaging into all new studies as this may permit a fundamental advance in the understanding of a particular disease.

Quality Assurance

- The ROG, through the QART committee and the QART office at EORTC Headquarters, will continue using the VODCA platform to develop QA procedures in all studies with RT. Patient data will be uploaded by the participating centers for review/validation by a member of the QA Team.

- The virtual phantom (VPP) will progressively be used for the credentialing of sites/investigators embarking on high tech radiotherapy protocols.
- An Image Guided Radiation Therapy (IGRT) Committee is starting to work within the QART Team and should provide an important contribution in the design of QART guidelines in the future.
- Cost effectiveness evaluation of QART is ongoing in close collaboration with the TROG.

Translational Research

In studies led by the ROG, translational research activities include the following:

- Study of the impact of 1p deletions in low grade glioma and the prognostic effect of these deletions on progression free survival in each treatment arm.
- Correlation of molecular characteristics of tumor tissue from malignant meningioma with the natural history of the disease and with the patient's response to radiation therapy.
- Identification of key molecular pathways for the future identification of patients most likely to benefit from radiation therapy in breast cancer, including the search for pharmacogenetic markers of relapse/outcome.
- Assessment of late treatment effects and prediction of lung toxicity. This is also important for patients receiving radiation therapy to the lungs in the treatment of breast cancer, malignant lymphoma, and esophageal cancer.

The methods used for these various translational research studies include the construction of micro-arrays, genotyping, and proteomics. They will be planned in close collaboration with the Pathobiology Group. The identified targets will be intermediate and high risk prostatic carcinomas and projects for early phase evaluation of combined radiation and targeted agents.

Radiation Therapist (RTT) Section

- The RTT section has been putting efforts into building a European network of RTTs. According to their specific field of expertise, RTTs are increasingly involved in participating in projects and in reviewing trial protocols.
- Parallel to the regular ROG meetings, the RTT section organizes international symposia with specific topics. They are participating actively in the QART strategic committee and in the new IGRT committee.
- The RTT section continues with the ambitious project on the delineation of Organs at Risk with the ultimate goal of producing an atlas of guidelines. This will be a very useful but an immense task! But we are up to the challenge!

Collaboration with other groups (EORTC and others)

EORTC Groups: The ROG currently collaborates with the EORTC Brain Tumor, Head and Neck Cancer, Lymphoma, Soft Tissue and Bone Sarcoma, Gastro-Intestinal Tract Cancer, Genito-Urinary Cancers, Breast Cancer, Lung Cancer, Pathobiology, and Imaging Groups.

Other groups: Collaboration is ongoing with the Radiation Therapy Oncology Group (RTOG) and the North Central Cancer Treatment Group (NCCTG) in the US, the NCI-C (Canada), the Scottish

Cancer Trials Breast Group, the Borstkanker Onderzoeksgroep Nederland (BOOG), the Intergroupe Francophone de Cancerologie Thoracique (IFCT), the Pan-European Trials in Adjuvant Colon Cancer (PETACC), the French Fédération Nationale des Centres de Lutte contre le Cancer (FNCLCC and UNICANCER) and the Trans-Tasman Radiation Oncology Group (TROG) from Australia.

www.eortc.org/research-groups/radiation-oncology-group

Structure of the Group

Chair	**W.T.A. van der Graaf, Nijmegen (NL)**
Secretary	**A. Gronchi, Milan (IT)**
Treasurer	**I.R. Judson, London (UK)**

Committees	
Chair Pathology	A.P. Dei Tos, Treviso (IT)
Chair Local Treatment	P. Rutkowski, Warsaw (PL)
Chair Systemic Treatment	H. Gelderblom, Leiden (NL)
Chair Translational Research	S. Bauer, Essen (DE)
Chair Imaging Subcommittee	*Vacancy*
Young Oncologists	A. Blesius, Paris (FR) until 2012
	L. Lindner, Munich (DE)

Membership and Principles

The Soft Tissue and Bone Sarcoma Group (STBSG) includes 47 full and five probationary members from 12 countries. The STBSG has a strict membership policy with regard to presence at group meetings, study accrual, and data quality. The pathological slides of all patients included in a clinical trial have to be reviewed centrally, and a level of 75% reviewed cases per trial and per center is required. The pathology subcommittee allocates the review of histological slides and/or blocks according to expertise and regional distribution to its members. All claimed responses have to be confirmed independently if response is the primary endpoint of the trial.

Meetings

Two meetings are held each year. The first day is dedicated to scientific questions. The last meetings were mostly dedicated to preclinical and translation research before the group meeting started. The STBSG Committees meet to review their work, objectives, and projects which are summarized during the General Meeting. The General Meeting is open to all members as well as to outside parties such as collaborators from the pharmaceutical industry and mainly concerns discussions of ongoing trials. Key members from other co-operative groups are invited to present the work of their group in order to foster intergroup collaboration. The business meeting is for full members only with strategic and financial matters to be discussed.

Recent Achievements

Important study results

- The activity of eribulin was investigated in the multistrata soft tissue sarcoma (STS) design, as was developed by the group previously. (Activity of eribulin mesylate in patients with soft-tissue sarcoma: a phase 2 study in four independent histological subtypes (Lancet Oncol 2011;12:1045-1052).

- The first phase III study with an angiogenesis inhibitor in STS was performed by the EORTC in collaboration with GSK and in many centers world-wide. The study met its primary end-point, and the study led to approval of pazopanib in STS (non-GIST, non liposarcoma) in 2012 by United States Food and Drug Administration and the European Medicines Agency (Lancet 2012; 379:1879-1886).
- The results of the randomized trial of combination treatment with doxorubicin and ifosfamide versus no adjuvant chemotherapy in 351 patients with intermediate and high-risk soft tissue sarcomas was accepted for publication (Lancet Oncol 2012, in press) .

Studies on a unique retrospective data base

The database of over 3000 patients treated with systemic chemotherapy for advanced soft tissue sarcoma (STS), and more than 2000 patients treated in first line setting, continues to prove extremely valuable. Under the supervision of Martine van Glabbeke and later on Monia Ouali, several database projects were published since 2011. These include:

- Performance status as the most powerful risk factor for early death among patients with advanced soft tissue sarcoma (Br J Cancer 2011;104:1544-50).
- Testing new regimens in patients with advanced soft tissue sarcoma: analysis of publications from the last 10 years (Ann Oncol 2011;22:1266-1272).
- First- line chemotherapy for malignant peripheral nerve sheath tumors (MPNST) versus other histological soft tissue sarcoma subtypes as a prognostic factor for MPNST: an EORTC soft tissue and bone sarcoma group study. (Ann Oncol 2011; 22:207-214).
- Angiosarcoma: state of the art and perspectives. (Crit Rev Oncol Hematol 2011: 80:257-263).
- Outcome of Patients with Platelet-Derived Growth Factor Receptor Alpha-Mutated Gastrointestinal Stromal Tumors in the Tyrosine Kinase Inhibitor Era. (Clin Cancer Res 2012;18:4458-4464).
- Prognostic factors in adolescents and young adults with high risk soft tissue sarcoma treated by adjuvant chemotherapy: a study based on the pooled EORTC clinical trials 62771 and 62931. (Eur J Cancer, in press).

Translational research

Translational research is not only conducted in the field of molecular characterization of sarcomas and detection of prognostic and predictive signatures, but also integration of recent developments in functional imaging is considered to be of major interest. It is particularly intended to attract young researchers working in this field and to open fields of collaboration between centers even outside trials. Applications can be made to the STBSG Board for initial ('kick-off') funding of research ideas up to 25.000€. Several projects are currently running.

Projects/Strategies for the coming years

The STBSG is repositioning its vision and strategy and will, next to being a network of excellent clinical sarcoma centers, also develop a network structure with a preclinical and translational research centers. The aim is to bring results of preclinical findings into the clinic, and this process may run faster if the EORTC plays a role in the subsequent clinical study. More than before, quality of life aspects will be integrated into upcoming clinical studies in order to gain a more in depth insight

into the value of the new treatments which are developed. Collaboration with the European sarcoma patient advocacy group (SPAEN) will be intensified.

Clinical trials 2011-2013

The following studies were open for accrual by STBSG in 2011-2012:

- **EORTC trial 62091**: A phase IIb/III multicenter study comparing the efficacy of trabectedin administered as a 3 hour or 24 hour infusion to doxorubicin in patients with advanced or metastatic untreated soft tissue sarcoma (TRUSTS). Study coordinator is Binh Bui-Nguyen, Bordeaux (Intergroup with US group, SARC).
- **EORTC trial 62092-22092**: A phase III randomized study of pre-operative radiation plus surgery versus surgery alone for patients with retroperitoneal sarcomas. Study coordinators are Sylvie Bonvalot, Paris (for STBSG), and R. Haas, Amsterdam. (Intergroup with Radiation Oncology Group).
- **EORTC trial 62063**: A phase III randomized study evaluating surgery of residual disease in patients with metastatic gastro-intestinal stromal tumors responding to imatinib mesylate. Study coordinator is A. Gronchi, Milano. Study was closed prematurely in 2011.

Beyond those mentioned above, several phase II and III studies are under consideration for activation in 2013, e.g. on first line therapy of soft tissue sarcoma, treatment of bone sarcomas, liposarcoma, uterine sarcomas (high grade and stromal cell sarcomas) and GIST.

Study results to be presented in 2012 and 2013

- **EORTC trial 62012**: A phase III randomized trial of single agent doxorubicin versus doxorubicin plus ifosfamide in the first line treatment of advanced or metastatic soft tissue sarcoma (closed to entry at 455 patients in May 2010). Study coordinator is Ian Judson. Results will be presented at ESMO 2012.
- **EORTC trial 62991-22998**: Phase II pilot study of moderate dose radiotherapy for inoperable aggressive fibromatoses. Study coordinator is Ronald Keus, Nijmegen. After entering the final patient in April 2008, the primary endpoint of the study of progression free survival at three years will be analyzed. Presentation at CTOS in 2012.
- **EORTC 62024** intergroup study. Intermediate and high risk localized, completely resected, gastrointestinal stromal tumors (GIST) expressing KIT receptor: a controlled randomized trial on adjuvant Imatinib mesylate (Glivec) versus no further therapy after complete surgery. Study coordinator: Paolo Casali.

Data base projects

All members of the STBSG are invited to join projects on additional studies related to specific EORTC trials or the database. By combining information of several studies together, the STBSG has unique properties to answer new and relevant clinical questions which can otherwise not be answered.

Collaboration with other groups

The STBSG is collaborating with other EORTC groups, such as the Radiotherapy Oncology, the Gynecological Cancers, the Imaging, and Quality of Life Groups.

European level grants were obtained for (previously) ContiCaNet (Chair: J.Y Blay) and EuroBoNet (Chair: P.Hogendoorn,) and the FP7 grant EuroSarc (Chair: JY Blay). The EORTC is participating in several work-packages.

The STBSG was involved in the founding of a World Sarcoma Network, a collaboration between European, American, and Australian sarcoma centers, to explore and develop trials in very rare sarcoma subtypes not manageable through current data centers or industry. The group is also committed to the development of intergroup studies with national sarcoma groups or in collaboration with large institutions and cooperative groups from the United States. The first transatlantic EORTC–SARC study, TRUSTS (EORTC trial 62091) is an example of this collaboration.

STBSG members are well represented on the Connective Tissue Oncology Society (CTOS) Board (Alessandro Gronchi, 2012 Conference Chair, Axel LeCesne, Piotr Rutkowski, Beatrice Seddon, and Paolo dei Tos).

As mentioned, the group will align more closely with SPAEN.

www.eortc.org/research-groups/soft-tissue-and-bone-sarcoma-group

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EORTC Headquarters

The EORTC is the only European organization that unites European cancer experts from all disciplines to establish international collaborations that facilitate, accelerate, conduct, and coordinate independent clinical and translational research on all types of cancer. Therefore the structure and functioning of EORTC Headquarters reflect the need to support its mission by providing expertise over a broad range of activities and research areas from strategic development to publication of research results.

Not only does EORTC Headquarters support the operational aspects of clinical research through protocol development, data and project management, regulatory affairs, and pharmacovigilance, but over the years EORTC Headquarters has become the essential partner of the EORTC Groups in implementing sound scientific strategy. This is achieved through expertise provided by the:

- Statistics Department;
- Medical Department;
- Translational Research, Radiotherapy, and Imaging Department.

Additionally, the Quality of Life Department develops and analyzes the quality of Life component of EORTC trials, the Early Project Optimization Department (EPOD) supports the development of the strategies for upcoming projects, and the fellowship program serves a unique role in supporting data optimization and utilization while also providing invaluable training to young oncologists.

There are also specific EORTC Headquarters units which support educational activities, contracts, legal and intergroups collaborations, as well as surveillance of quality assurance and control.

Over the years, EORTC headquarters has supported a large number of clinical trials addressing early and late stage development scientific questions as well as a number of scientific and methodological research projects, the vast majority of which are supported by the EORTC Headquarters Fellowship Program.

Implementation of the EORTC Scientific Strategy

The EORTC scientific strategy as defined and approved by the EORTC Board evolves constantly as the organization reevaluates its program in response to the changing needs of the cancer clinical trial landscape. While this might not necessarily be apparent to the EORTC Groups which have long term agendas and a multitude of activities, EORTC Headquarters is confronted with a rapidly changing environment and needs to assess why and how certain activities are performed. In the past ten years the main parameters which have had a profound impact on the organization and its functioning are:

- Implementation of molecular biology for personalized medicine;
- Evolution of the European regulatory framework;
- Expanding intergroup cooperation;
- Increased partnerships with other learned societies such as with those in imaging and pathology.

In response to the above, the EORTC scientific strategy is now centered on clinical research questions which require not only an international and multi-disciplinary set up but also require the integration of biology, pathology and imaging. This has all been done in order to optimally develop therapeutic strategies with a more complete understanding of the biology of the diseases and the mechanisms

of action of the therapeutic interventions; our aim is to apply the appropriate treatment to the right patient at the required time.

The EORTC Scientific Strategy now sustained by EORTC based technical expertise platforms

The implementation of new clinical research approaches would not be possible without innovative support which integrates knowledge gained from biology and images. A challenge, therefore, is to successfully integrate clinical, pathobiological and imaging data to gain an optimal understanding of the biology of the disease and to support development and therapeutic decisions.

To achieve such goals, EORTC Headquarters now has a fully operational imaging platform which allows upload, central review and quality assurance of images in real time, regardless of whether these were obtained by radiology or nuclear medicine. In a similar spirit, new biobanking policies allow the development and conduct of a new generation of trials based on tissue acquisition and biomarker determination. This has been made possible by a close cooperation between the Information Technology Department and the Translational Research, Radiotherapy and Imaging Department. The level of expertise that has been developed has allowed EORTC Headquarters to successfully obtain support for a major Innovative Medicine Initiative project for the development of imaging biomarkers.

Modern clinical research cannot be addressed without specific partnerships

While EORTC, and more specifically EORTC Headquarters, remain a unique international, European based clinical trial organization, the new landscape of research shows that what had been done by the organization independently for the past 50 years now requires additional and /or more structured cooperation and partnerships with other learned societies and with the pharmaceutical industry sector. Due to the emergence of new academic groups as well as due to the fragmentation of tumors based on molecular characteristics, cooperation with other investigator networks is strategically important for rapid patient recruitment and more effective clinical/translational research.

Consequently, EORTC Headquarters has established partnerships to set up the new technology platforms, such as with the European Association for Nuclear Medicine, the European Society for Radiology, and the European Association for Pathology. These learned societies benefit from the EORTC's expertise in clinical research, while the EORTC can implement complex programs taking into account all quality assurance parameters for the concerned disciplines.

The number of patients included in intergroup studies has been steadily increasing to the point where intergroup studies account for roughly one third of EORTC activities. Taken together with the complexity of the regulatory framework, this has prompted EORTC Headquarters to set up liaison offices in France, the United Kingdom, and Poland, while Germany and Spain have expressed interest in setting up liaison offices.

Cooperation with the pharmaceutical industry sector is a key to innovation

The EORTC has a series of trials which were successfully conducted in partnership with industry and which jointly changed practice. These serve either prospectively or retrospectively for drug registration which is in the best interest of all parties and leading to therapeutic improvement for patients.

Moving forward, new forms of partnerships between industry and academia will need to be envisioned as modern clinical trials demand long term maintenance of technical and cross validated infrastructure which is neither in the remit nor in the capacity of industry. New agents can be best and more rapidly developed if studied in such high quality academic environments. Molecular sub-division of tumor entities imposes the formation of efficient and transnational networks for large screening programs for complex trials which cannot be administered outside an optimally controlled and well-oiled infrastructure with the aim of avoiding duplication of screening efforts by industry.

Complementary commercial and academic agendas need to evolve to ensure the principles of independence that are so critical for the scientific and patient community. Both parties need to address data access policies for shared knowledge and stimulate scientific thinking while new approaches to Intellectual Property challenges need to be developed. While the integration of agendas alongside efficient developmental activities and avoiding duplication of effort should be a cost efficient approach, funding will remain a major challenge for complex, cutting edge clinical and translational research.

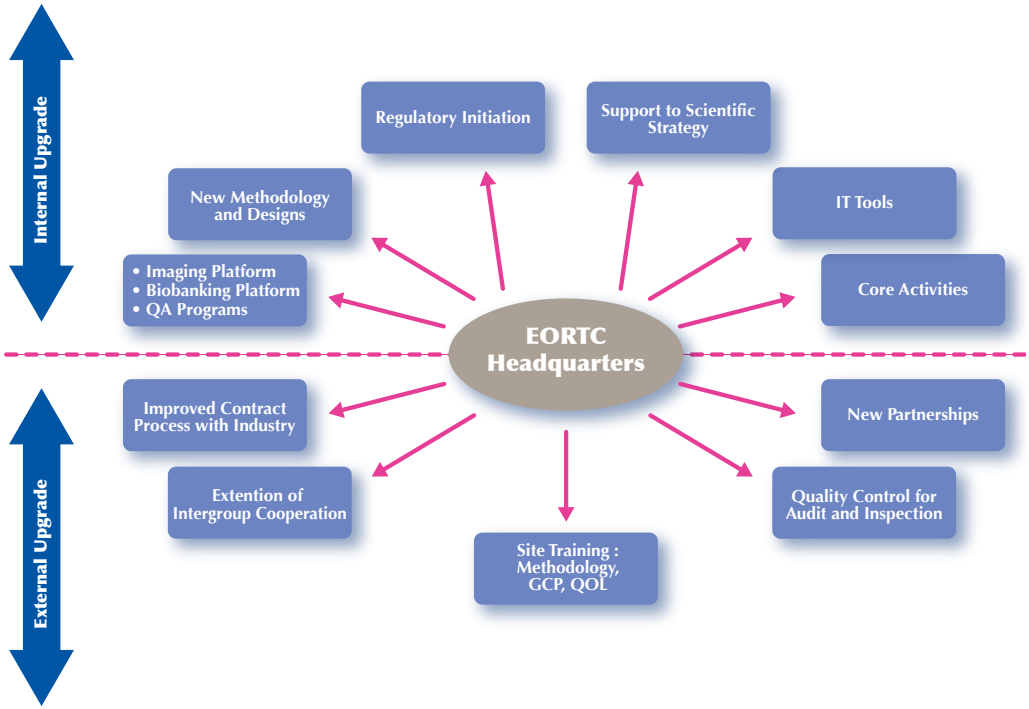
Dating back to the Phase II Unit mentioned previously, the EORTC has made substantial progress in facilitating interactions with industry for drug development. Today, the operations to conduct clinical trials and data exchange policies are wide open with respect to partnership models. That said, it is critical for both industry and academia, when partnering on trials which go beyond the single drug development approach, that the principles of academic independence are respected. The forms and the methods of cooperation with industry are constantly evolving but are based on a good balance between a few criteria ensuring academia independence and sets of procedures for full visibility by industry.

Working closely with patient organizations brings a critical eye to EORTC activities

The EORTC has established relationships with numerous patient organizations and cancer leagues throughout Europe. In these relationships, the EORTC benefits from the expertise of patients for making information sheets and informed consent forms more patient friendly and for the dissemination of information concerning progress in EORTC cancer clinical trials. Further insights on other forms of cooperation are being explored and will lead to specific working meetings. A number of continued activities have been revisited and upgraded. In addition, since 2012, EORTC has created an open forum for patient representatives to attend a one day introduction to EORTC studies.

The way forward

EORTC Headquarters has evolved to become a unique European clinical trial infrastructure with multi-faceted functions which embraces all the challenges of modern cancer clinical research for the benefit of all patients with cancer.



Reports from the EORTC Headquarters Departments, Units, and Offices are presented in the following pages:

Early Project Optimization Department

The Early Project Optimization Department (EPOD) was created in 2008 in response to the global EORTC scientific strategy and the new EORTC project prioritization process. EPOD's roles are multiple and flexible, to enable responding to changing demands. Selected roles are summarized below, however, EPOD support is broader than detailed below and remains on request.

How can EPOD be useful to an EORTC Disease Research Group?

EPOD can help:

- set up a global strategy for a given disease or subpopulation;
- optimize a project to meet the EORTC scientific strategy;
- help to select a pathway/a target of interest;

- optimally select an agent by providing details of all agents against a particular target and their development status;
- help mature translational research projects both scientifically and operationally;
- facilitate Pharmaceutical company interactions via regular contact and by organizing partnership meetings and advisory boards;
- optimize sharing of expertise within EORTC by facilitating the contact and communication between different Disease Orientated Groups, modality based groups (Radiation Oncology Group, Cancer in the Elderly Task Force, Imaging Group) and the Translational Research Division;
- harness the expertise of peer review committees, e.g. New Drug Advisory Committee and Translational Research Advisory Committee.

Operationally, EPOD serves as the port of entry for new projects into the EORTC and helps manage these projects during their early phase.

EPOD can provide support to disease orientated groups for the development of their scientific strategy, either globally or on a specific aspect or project. This will be defined by the patient population, the available treatments, the group's ongoing trials, the drug pipeline, and the biological markers of the disease. A project proposal strategy would concentrate on the specific population in need or concept and include new drugs, drug combinations, multimodalities, screening platforms, and translational research proposals specifically tailored for the population/proposal. By providing context and strategy, the group strategy facilitates the development and improves the quality of project proposals.

To date, EPOD has completed full strategy assessments with the Cutaneous Lymphoma Task Force, as well as for ovarian cancer, Hodgkin's lymphoma, Children's Leukemia, adult acute myelogenous leukemia (AML), pancreatic cancer, colorectal cancer, non-small cell lung cancer, mesothelioma, head and neck squamous cell carcinoma, cutaneous melanoma, and ocular melanoma, adrenal corticocarcinoma and thyroid cancer and drug combinations with radiotherapy. Several strategies have also been completed addressing specific subpopulations, e.g. bone metastases, brain metastases, and elderly breast cancer.

EPOD also provides help to optimize project proposals whether from disease orientated groups or related to specific calls for projects (e.g. NOCI 2010 call). EPOD orchestrates early and timely involvement of experts and key opinion leaders (New Drug Advisory Committee, Translational Research Advisory Committee, Translational Research Division, Imaging Group, etc.) and ensures that interactions with industrial partners are developed and optimized. The intent is to improve the quality of project proposals prior to review by the EORTC Board and increase the overall efficiency of project development.

As an entry point for new proposals and in its role of facilitating communication and sharing of expertise within the network, EPOD can be contacted for a wide variety of questions and support.

Protocol Development Unit

The Protocol Development Unit (PDU) has three main roles:

- supporting the Protocol Review Committee (PRC) Chair by coordinating the independent external scientific review of new clinical study proposals 'outlines';

- supporting the study team in the development of study protocols and EORTC Group Specific Appendices (GSAs) for Intergroup studies;
- coordinating the review, approval, and implementation of protocol amendments.

Coordinating the independent external scientific review of new clinical study outlines

The PDU supports the PRC Chair by coordinating the independent external scientific review of new clinical study proposals 'outlines'. This involves coordinating the review with PRC reviewers, EORTC committees, the US National Cancer Institute Cancer Therapy Evaluation Program (NCI CTEP) when applicable, and independent external experts. The PDU reports the reviewers' comments to the PRC Chair for their decision. The PDU also interacts with study coordinators (SC), for example, in collecting signed SC responsibilities and conflict of interest forms.

Providing support during study protocol and GSA development

The PDU maintains an extensive library of protocol chapters, template chapters, and guidelines to facilitate protocol development. Once the study team has chosen which chapters and templates they require, the PDU provides all the technical and administrative support in protocol development. When the protocol is deemed final by the study team, the PDU organizes a review to check for quality and consistency prior to protocol approval.

Coordinating the review, approval, and implementation of protocol amendments

The PDU coordinates the review of scientific amendments for the PRC Chair and the approval of administrative amendments. The PDU also implements amendments and publishes new protocol versions which are made available to investigators on the EORTC website.

International Regulatory Affairs / Intergroup Office

The International Regulatory and Intergroup Office follows-up on the legal framework applicable to EORTC clinical research at the EU and national levels, provides EORTC Headquarters with critical analyses of existing legislation, formulates proposals for eventual further recommendation to legislators, and advises and provides assistance to several units within EORTC Headquarters. The EORTC liaison offices and country specific development strategies are instituted and coordinated by this office.

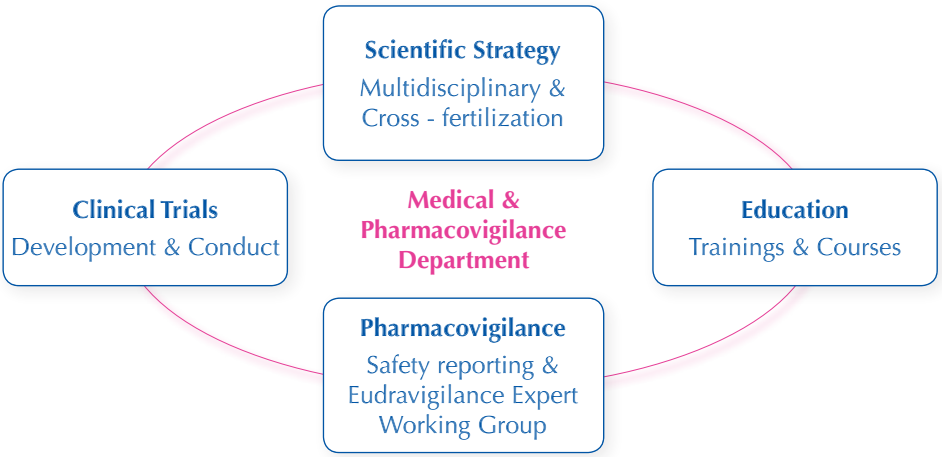
The EORTC places a high priority on patient involvement and activities. A database of patient organizations is maintained by the International Regulatory and Intergroup Office to ensure regular communication with these organizations and inform them about EORTC activities, available courses, and relevant research results. Several patient organizations and panels are involved in trial specific reviews as well as other activities which provide valuable support to the EORTC clinical research mission.

This office combines the unique legal and operational expertise required for large intercontinental intergroup collaborative clinical research projects, the support of intergroup collaborations at the EORTC, and the general activities of several umbrella organizations such as the Gynecological Cancer Intergroup and the Breast International Group. In order to specifically support collaborations with groups supported by the United States National Cancer Institute, the International Regulatory and Intergroup Office coordinates the work of the EORTC Institutional Review Board which, among

other missions, annually reviews all projects run in collaboration with these groups and maintains the Federalwide Assurance application.

Medical and Pharmacovigilance Department

This Department includes the Medical and Pharmacovigilance units.



Medical Unit

Medical unit provides support to the scientific strategies elaborated by the EORTC research groups, the conduct of clinical trials, and education.

Scientific strategy

Clinical Research Physicians (CRPs) support the EORTC Groups in the elaboration of their scientific strategies to improve standard of care. The emergence of targeted therapies and the progress in fundamental science, especially in genetics, molecular and cell biology and imaging technologies, requires a multidisciplinary clinical research approach. CRPs contribute to build collaborations between scientists and clinical investigators in various areas such as translational research and imaging, and help to develop strong interactions between the stakeholders (academic groups, industry, etc.). Through their various activities with different EORTC groups, CRPs facilitate cooperation and the cross fertilization of ideas among the groups.

Clinical trial activities

CRPs provide medical expertise and support for the development, implementation, conduct, and reporting of EORTC clinical trials. They work together with Data Managers, Projects Managers, and Statisticians as part of the EORTC Headquarters teams supporting the studies carried out by the EORTC Research Groups. They also contribute to the outline and writing of protocols and in the design of case report forms. Throughout the study, they make an active contribution to the safety reporting.

Education

The Medical Unit develops and conducts training programs for the EORTC staff. CRPs contribute to courses and workshops organized by the EORTC and External partners.

Pharmacovigilance Unit

The Pharmacovigilance Unit (PVU) is responsible for reporting safety information in a rapid and secure manner to the Competent Authorities, Ethics Committees, Investigators, and the European Medicines Agency (EMA). Towards this end, PVU wrote and implemented standard operating procedures and infrastructure for Serious Adverse Event (SAE) collection and reporting. Protocol specific chapters were written, Case Report Forms were created, and training was given.

In 2010 the PVU developed, validated, and implemented a new safety software system called SAfE. It allows the PVU to collect all SAEs, facilitate the reconciliation with the clinical database, report electronically to the Competent Authorities, EMA, and pharmaceutical companies, and facilitate the creation and tracking of annual safety reports.

It is necessary to be kept informed of all changes in the laws and regulations, the Clinical Trial Directive and its specific safety-related guidelines, which affect current working procedures. It is therefore a privilege that the PVU is also represented at the Eudravigilance Expert Working Group with the aim of ensuring that new guidance documents on the safety reporting in clinical trials are also feasible for non-commercial sponsors.

Translational Research, Radiotherapy & Imaging Department

The Translational Research, Radiotherapy and Imaging Department (TRI) provides support to EORTC trials that address questions that directly contribute to defining new standards of care, specifically, trials that include a strong translational research component that advances the fundamental understanding of a particular disease.

Translational Research Unit (TRU)

Building on the wealth of experience in the EORTC network on translational research (TR), the TR team plays a central role in implementing a TR infrastructure to stimulate and support high quality TR projects and integration of biomarker testing into EORTC clinical trials. The mission of the TR team is to support high quality TR through close interaction with the EORTC Translational Research Advisory Committee (TRAC), the Translational Research Division Groups (e.g. the Pathobiology, Pharmacology and Molecular Mechanisms, and Imaging Groups) and the EORTC Headquarters units.

The TR team coordinates with TRAC at an early stage of protocol development for the stimulation of TR concepts and for quality assurance discussions. This is in addition to the regular EORTC Protocol Review Committee linked function whereby TR proposals included as part of the clinical trial protocol are reviewed to ensure adequacy of protocols in relation to human biological materials (HBM) collection and TR projects. The TR team also works with the TRAC for review of new TR concepts that require access to HBM but were not specified in the clinical protocols (retrospective TR projects). The TR team also coordinates TRAC review and progress reporting of all ongoing Board approved EORTC TR projects.

To streamline processes, the TR team has introduced a system to distinguish between TR that forms an integrated part of the trial design ("integrated TR") and separate TR studies that prospectively or retrospectively use HBM collected within the scope of the clinical study but are not essential to the

trial design ("correlative TR"). TRAC review is coordinated to meet the different needs of these two types of TR.

Ongoing projects: human biological materials collection

The emphasis remains on the prospective collection of HBM from patients entering EORTC trials to investigate critical molecular pathways associated with tumor progression and metastasis and assessment of molecular determinants of treatment efficacy.

Pilot projects, such as the EORTC 22043-30041 prostatic carcinoma trial and the TR and biobanking study in Children's Leukemia, EORTC 58081, have been initiated and are ongoing. To promote harmonization, standard operating procedures and guidelines for HBM collection and management have been implemented. In conjunction with the EORTC Project Management Unit, service providers have been audited and selected to enable secured sample storage, shipment and processing.

SPECTAColor, a new initiative, is a screening program for advanced colorectal cancer. It is a clinical trial platform in which access is based on molecular cancer characteristics. SPECTAColor is at the core of these processes and benefits from these achievements.

The TR team continues to support the EORTC's role as a partner to an FP6 EU CHEMORES project (chemo-resistance in melanoma and lung cancer) initiated in 2006 which established a centralized tissue collection of HBM in several melanoma trials (the EORTC 18951, 18992 and 18032 trials). A pilot phase of the laboratory studies in genomic profiling gave encouraging results that the profiling technology was performing well on paraffin embedded formalin fixed materials. The project is now in the final stages of tissue characterization and analysis.

In collaboration with the Project Management Unit and Regulatory Affairs Unit, the TR team has set-up a harmonized process for the submission of retrospective access to HBM projects to the EORTC. The TR team ensures the coordination of these TR projects between TRAC, EORTC groups and ethical bodies.

Since 2010, almost 20 projects are now following the new process from various EORTC groups (for example brain, lymphoma and breast).

The above initiatives, as well as other EORTC groups' experiences, have served as models to develop templates, standard operating procedures (SOPs), ethical and legal frameworks and logistical checklists forming the basis of the EORTC policy "Collection and use of Human Biological Materials" (POL020).

Human biological materials collection, storage and use

Access to appropriate HBM, e.g. tissues, blood or other bodily fluids in both sufficient quantity and quality, is essential to performing TR, and importantly, HBM must be linked to high quality, full, clinical datasets. The TR team, in strong collaboration with the EORTC Pathobiology Group (PBG), have developed an updated policy for HBM collection and use which was released in March 2012. This framework aims to progressively develop EORTC bio-resources and to support investigators' TR and pathology review programs by securing the most up to date international standards in HBM collection.

The policy principles are applicable to the collection, storage, and use of HBM and associated data from patients participating in EORTC clinical studies. The updated policy promotes best practice in biobanking and is in accordance with current international legal and ethical standards for storage

and future use of HBM. Key topics including the chain of custodianship of HBM collected from patients enrolled in EORTC clinical studies, ethical principles, confidentiality and data protection, access to HBM, criteria for establishment of EORTC group biobanks, and publication of resulting research are covered. This policy builds on the extensive expertise of the EORTC groups, the PBG, pilot projects, and EORTC tumor bank activities. Together with the PBG, a practical biobanking checklist for quality management of biobanks has been developed and is now being used to establish biobanking facilities in several disease oriented EORTC groups. Also in collaboration with the PBG and TRAC, the EORTC HQ has developed practical tools for the prospective collection of HBM, including a checklist to support logistical planning and HBM collection set up.

Through these HBM collection initiatives, the EORTC will be able to prospectively collect detailed molecular data to complement its clinical and quality of life databases, its radiotherapy database, and its recently established imaging database. These resources, in toto, will add further dimensions to the analysis of endpoints in clinical trials.

Exchange of expertise and interaction in the EORTC network

The TR team has also been active in training and dissemination of best standards for HBM collection together with the PBG through presentations at the EORTC methods, an OECI course "Biobanking for cancer research: Rules and Roles", a workshop at the 22th EORTC-NCI-AACR symposium on «Molecular Targets and Cancer Therapeutics» held in November 2010, participation in the FEBS «Advanced Lecture Course on Translational Cancer Research» in 2011 and participation in 2012 «Markers in Cancer» in Florida.

IT systems:

HBM tracking systems (Samples tool)

The TR team is working closely with the IT Department and Project Management Unit for the in-house development of integrated tools for managing HBM shipments and HBM data collection which is being piloted in the EORTC 58081. This tool is called "Samples" and replaces the previous Virtual Tumor Bank (VTB) system. Samples is now being used for tracking HBM from eight EORTC studies.

Virtual Microscopy

The Virtual Microscopy system is currently used for the central pathology review program in collaboration with the EORTC Brain Tumor Group in the following studies:

- EORTC trial 26951 (slides for 275 patients);
- EORTC trial 26882 (slides for 416 patients, anaplastic oligodendroglioma, anaplastic astrocytoma, mixed oligoastrocytoma, anaplastic mixed oligoastrocytoma, astrocytoma, oligodendroglioma, and glioblastoma);
- as well as uploading slides from EORTC trial 26981 (slides for 314 patients, glioblastoma multiforme).

In total approximately 1680 virtual slides from these three trials have been centralized and will be made available through secure EORTC servers with associated forms to support the work of the panel of pathologists. This resource will be used to improve histological diagnosis of glioma typing and grading by better defining key histological features and panel review.

The TR team is investigating new TR projects in the frame of EORTC clinical trials, where the use of virtual microscopy might be of added value.

Quality Assurance in Radiotherapy (QART)

QART at the EORTC builds on 30 years of experience of the EORTC Radiation Oncology Group (ROG) in pioneering QART in an international clinical trial setting. The QART team develops, administers and analyses Quality Assurance procedures with the aim of ensuring the quality of radiotherapy across the broad spectrum of EORTC trials. The QART team at EORTC Headquarters includes the QART Officer, the QART manager, the Emmanuel van der Schueren Fellow (supported by the Vlaamse Liga tegen Kanker) and the ROG Clinical Research Physician.

The QART team is currently overseeing radiotherapy aspects of thirteen ongoing and eight forthcoming trials, collaborating with the Brain Tumor, Breast Cancer, Head and Neck Cancer, Gastrointestinal Tract Cancer, Genito-Urinary Tract Cancer, Lymphoma and Soft Tissue-Bone Sarcoma groups. The QART team remains committed to developing new strategies to address the complexity of advanced radiotherapy techniques with the knowledge that high quality treatment within clinical trials ensures the quality of clinical trial results which will improve cancer therapy.

Imaging

Medical imaging is a key technology for non-invasive assessment, accelerating the development of, and guiding the use of new therapeutic options. Reliable, non-invasive staging of disease and response to therapy is crucial for patient management. The Imaging team ensures proper implementation of the different medical imaging modalities, protocol and imaging guidelines compliance, quality control of scans, analysis of deviations and process improvements for EORTC clinical trials.

The TRI aims to improve the quality and consistency of evaluation of cancer treatment within EORTC clinical trials through imaging technologies including CT, PET[-CT], MRI, used for treatment definition for Radiotherapy, staging, prediction and evaluation of response, or pathology.

The TRI is actively engaged in the Innovative Medicines Initiative Quantitative Imaging in Cancer: Connecting Cellular Processes with Therapy project (QuIC-ConCePT), whose aim is to qualify imaging biomarkers of tumor cell proliferation, apoptosis, and necrosis.

Quality of Life Departement

The Quality of Life Department (QLD) is responsible for developing and analyzing the quality of life (QOL) component of EORTC clinical trials and acts as a support for selective projects undertaken by the EORTC Quality of Life Group (QLG). The QLD also has an ongoing and active research program in a number of key areas in the field of QOL and symptom research.

EORTC trials

The QLD continues to collaborate actively with the EORTC clinical groups and supports the implementation of QOL into clinical trials. During 2010-2011 QOL studies were activated in several new clinical trials. Three large scale phase III clinical trials with QOL data were published in collaboration with various EORTC groups including the Radiation Oncology, Melanoma, and Gynecological Cancer Groups.

Patient Reported Oucomes and Behavioural Evidence research

During 2010-2011 the QLD has continued to work on the Patient Reported Oucomes and Behavioural Evidence (PROBE) research project which is funded by the Pfizer Foundation as part of its Global Health Partnership Program. PROBE's aim is to explore QOL and psychosocial issues in cancer patients. During this period, research findings from PROBE resulted in ten peer reviewed abstracts being presented at conferences such as ASCO (American Society for Clinical Oncology), ISOQOL International Society for Quality of Life Research) and ISPOR (International Society for Pharmacoeconomics and Outcomes Research). Furthermore, in November 2011 an EORTC Conference, Quality of Life, Symptom Research, and Patient Reported Outcomes in Cancer Clinical Trials, was hosted in Brussels at the European Parliament for three days. This event presented results from PROBE as well as views of key opinion leaders from around the globe and was attended by over 300 health care professionals. All presentations at this meeting were recorded and are accessible online (www.eortc.be/probe/videos.htm). The 2012 EORTC QOL Conference will be hosted again at the European Parliament on 17-19 October and has received funding from the European Union in the framework of the Health Programme.

In 2011 a research grant was awarded from the Fondation Belge contre le Cancer to fund a three year PROBE Fellowship in statistics.

Collaboration with the Quality of Life Group

The QLD maintains a close relationship with the QLG and participates in the development process of various new QLG modules such as Vulva, Breast Reconstruction, Melanoma, etc. In early 2011, a new project was set up to collect and store data from the development of previous modules and to develop a standard template and establish guidelines for the development of new modules.

The QLD continues to receive a constantly rising number of worldwide requests for EORTC QOL measures. In 2011 alone, the QLD received 2300 new download requests for academic use and more than 100 contracts were signed with industry partners.

By the end of 2011, the EORTC core questionnaire was translated into 85 different language versions. In the years 2010-2011, over 150 new language versions were finalized, and the total number of translations available for use exceeds 700 with more than 100 additional translations in progress. Much time and effort are devoted to checking translations, harmonizing response scales and items, and achieving consistency across translations and cultural adaptations. The Translation Team is also busy with research in the field of methodology of patient reported outcomes translations with presentations at international conferences and some recent publications on cultural issues, reconciliation etc.

After ten years, the QOL website's structure has been redesigned in a more accessible and user-friendly way. With 400 visits per week, the website represents the main interface between the QLG/QLD and the larger community of QOL researchers, patient groups, industry. The new QOL website aims to improve the EORTC QOL visibility by delivering up-to-date information and cutting-edge contents on QOL measures.

Other research activities

In addition to the PROBE scientific output noted above, the QLD has successfully presented 20 peer reviewed abstracts at international scientific congress, e.g. ASCO, UICC (Union for International Cancer Control), and ISQQOL. Furthermore, in collaboration with many EORTC Groups and

International bodies, a total of 12 articles were published in peer reviewed journals such as the Journal of Clinical Oncology. Two book chapters on QOL research methodology were also published in 2010-2011. Five articles on topics such as QOL in relation to clinical significance of QOL results and QOL policy are currently in press.

Project Management, Budget Development & Regulatory Department

The Project Management, Budget Development, and Regulatory Department:

- provides support to the EORTC Membership Committee by centralized management of membership application and approval process;
- provides expertise and support to the IT Department for "management tools development" currently a Clinical Trial Management System is being integrated across the various existing management systems at the EORTC Headquarters;
- provides budget estimates and final, related to the conduct of clinical trials in close collaboration with the Contracts, Accounting and Finances Reporting Unit;
- supervises the activities of the Project Management, Regulatory, and Clinical Trials Assistants Units.

The Project manager is the central contact person for the EORTC Research Groups and study participants. He/she coordinates all activities related to the management of the clinical trials from development till publication.

The Regulatory Unit coordinates and performs the submission of the clinical trials for activation following the applicable international and national regulations and ethical requirements. It monitors changes in the conduct of the trail which require notification to the regulatory bodies including protocol amendments, reports the end of trail to the appropriate regulatory bodies, keeps updated on the changes of the regulatory environment on a regular basis.

Clinical Trial Assistants are responsible for maintaining adequate filing of the Trial Master Files and provide administrative and secretarial support to the Study teams.

Statistics Department

Description

The statisticians within the EORTC Headquarters Statistics Department provide methodological and statistical support for the design, implementation, conduct, analysis, and reporting of EORTC clinical trials and other scientific projects. They work together with Data Managers, Project Managers, and Clinical Research Physicians as part of EORTC Headquarters teams supporting the studies carried out by the EORTC Groups.

In particular, the statisticians provide advice to the EORTC Groups and study coordinators on the optimal statistical design to be used in the conduct of their studies and help to write the protocol outline, the full protocol, and the case report forms. They interact with Data Managers to ensure data quality control, carry out interim and final statistical analyses, and help to prepare the resulting publications and presentations. The statisticians also support EORTC Groups in preparing grant applications for EU funding.

Jan Bogaerts succeeded Richard Sylvester as Head of the Statistics Department on 01 September 2010. In January 2012, Jan added to his responsibilities when he was appointed EORTC Headquarters Vice-Director of Methodology. As of March 2012, Laurence Collette, Associate Head of the Statistics Department since 2006, became coordinator of the EORTC Independent Data Monitoring Committee (IDMC), a position she took over from Richard Sylvester. Since his official retirement on 31 May 2012, Richard continues on a one day per week basis to provide EORTC Headquarters support to the EORTC Genito-Urinary Cancers Group as Senior Statistical Scientist. In June 2012, there were eleven statisticians and three statistical fellows at EORTC Headquarters. One of the fellows will become Junior Statistician in the course of 2012. Each statistician works with one or more of the clinical groups, and most have specific applied methodological research projects.

Achievements

The primary achievements of the Statistics Department remain the ongoing support of all group studies, interim and final analyses, and manuscripts which are described throughout this report.

Training and teaching

A twice monthly meeting of the 'Stats Club' ensures that the statisticians remain current with clinical trial methodology. They also participate as faculty members in various courses organized either by the EORTC (for example the annual four day course 'Clinical Trial Statistics for Non-Statisticians' which is organized by the Statistics Department, and the four day course 'Methodology of Cancer Clinical Trials' organized by EORTC Headquarters) or together with other cancer research organizations, for example the joint ECCO-AACR-EORTC-ESMO Workshop `Methods in Clinical Cancer Research' held annually in Flims, Switzerland. One statistician (C. Coens) is also providing statistical guidance to fellows in the Quality of Life Department. In collaboration with the EORTC Headquarters Data Management and Information Technology Departments, the Statistics Department is currently taking the steps needed to bring the EORTC clinical trials to the CDISC standards.

Processes

The more senior statisticians have additional administrative and scientific responsibilities, for example, they serve on EORTC committees such as the IDMC and assist in the development of a number of EORTC Policies pertaining to data sharing, publication of results and interim monitoring. The Statistics Department maintains close contacts with other academic statistics departments and groups and currently has active scientific projects with:

- Institut Curie: phase I for non-cytotoxic agents
- Institut Gustave Roussy: teaching, exchange of results, meta-analyses
- Centre Georges François Leclerc, Dijon; Centres de Traitement des Données de l'Institut Bergonié, Bordeaux, du Centre Val d'Aurelle, Montpellier, et du Centre Oscar Lambret, Lille: DATECAN project (Guidelines for definitions and analyses of time to event data in cancer randomized clinical trials)
- Jules Bordet Institute/Université Libre de Bruxelles: scientific presentations, teaching collaboration
- Université Catholique de Louvain: research on frailty models together with Daegu Haany University, South Korea.
- Université de Liege: research on partial proportional odds model with application to Quality of Life data
- Leiden University Medical Center (LUMC): collaboration on research projects, teaching

- Université de Bordeaux Segalen (INSERM Unit 897): collaboration on research on interval censoring methods and measures of performance of prediction models

Corneel Coens is a member of the UK Clinical Trials Awards and Advisory Committee (CTAAC). Murielle Mauer is a member of the Committee for Strategic Orientation for the French Union against Cancer (UNICANCER). Stefan Suciu is a core member of the external scientific advisory group for oncology at the European Medical Agency and also a member of the EBMT (European Bone Marrow Transplantation) Statistician Subcommittee. Richard Sylvester is a member of the European Association of Urology (EAU) Guidelines Office Board and the EAU Non Muscle Invasive Bladder Cancer Guidelines Committee. Jan Bogaerts and Saskia Litière are key members of the RECIST (Response Evaluation Criteria In Solid Tumors) committee. Statisticians commonly peer review work for major journals and are members of a number of editorial boards. Several senior statisticians are part of other organizations' IDMC boards.

The EORTC Statistics Department, through the EORTC Data Sharing procedure, currently contributes data to 29 meta-analyses, among which the following resulted in full publications in 2011 or 2012:

- A study of patterns of care for local therapy of locally advanced breast cancer (Breast 2011;20(2):145-50);
- A study to characterize and document outcome of acute lymphoblastic leukemia patients who failed to response after induction through contribution to the Ponte-di-Legno Group (N Engl J Med. 2012;366(15):1371-81);
- A pooled analysis of randomized trials to develop nomograms for predicting local recurrence, distant metastases, and overall survival in patients with locally advanced rectal cancer (J Clin Oncol 2011;29(23):3163-72);
- Update of the breast cancer meta-analyses through assessing the effect of radiotherapy after breast conserving surgery for early breast cancer through Early Breast Cancer Trials Collaborative Group (EBCTCG) in Oxford (The Lancet 2011;378(9804):1680 - 1682).
- Meta-analysis assessing the relevance of breast cancer hormone receptors and other factors to the efficacy of adjuvant tamoxifen (EBCTCG, The Lancet 2011;378(9793):771 - 784).
- A meta-analysis of trials to study the prognosis of elderly patients with first treatment for primary central nervous system lymphoma meta-analysis of chemotherapy in head and neck cancer (MACH-NC) (Radiother Oncol 2011;100(1):33-40).
- A meta-analysis of radiotherapy for head and neck carcinoma (MARCH, J Clin Epid 2011;64(9):985-992).
- A systematic review and meta-analysis of randomized trials of central nervous system directed therapy for childhood acute lymphoblastic leukemia (Pediatr Blood Cancer 2012 Jun 12. doi: 10.1002/pbc.24228).

EORTC Statisticians and statistical fellows are also directly involved or leading some further research projects:

- A pooled analysis of trials of radiation therapy for anal cancer (PARADAC) is being completed by one of the statistical fellows and the EORTC Radiation Oncology Group.

- Another major methodological project is ongoing to collate databases of phase I studies of single agents molecular targeted agents; to redefine dose limiting toxicities is expected to complete by end of 2013. A fellow and a senior statistician are involved.
- An overview of the effect of bacillus Calmette Guerin for the treatment of non muscle invasive bladder cancer (Int J Urol 2011;18 (2):113-120).
- Together with former statistical staff now at Belgian universities and with Korean colleagues, the methodology of frailty models was (Statist Med 2011;30:2144-2159);
- Prognostic importance of serial assessment of S100B in stage IIb - Stage III melanoma patients included in EORTC trial 18952 (Eur J Cancer 2010; 47(3):361-368), and the assessment of changes of ferritin and CRP levels in melanoma patients treated with adjuvant interferon-α or observation in EORTC trial 18952 (Melanoma Res. 2011;21(4):344-51);
- A position paper about adaptive sample size reestimation in phase III clinical trials (Eur J Cancer 2012;48(9):1386-91);
- A pooled analysis of four EORTC trials assessing outcome of women versus men with stage I/II cutaneous melanoma (J Clin Oncol 2012;30:2240-2247).
- The evaluation of the incidence of second neoplasms subsequent to therapy for childhood acute lymphoblastic leukemia or lymphoblastic lymphoma (Pediatr Blood Cancer 2011;57:119-125).
- Prognostic significance of the initial cerebro-spinal fluid involvement of children with acute lymphoblastic leukemia treated without cranial irradiation (EORTC 58881) (Eur J Cancer 2011;47 (2):239-247).
- The RECIST version 1.1 (Response Evaluation Criteria in Solid Tumors, EJC 2009) warehouse of detailed tumor measurement information (16 Phase III trials, over 10,000 patients) continues to be maintained at EORTC Headquarters and preparations are ongoing for the next update. Analyses are being performed to study the components of progression as explanatory variables for overall survival in the current RECIST database (presented at ASCO 2012). Furthermore, efforts are ongoing to collect additional data to assess whether RECIST 1.1 can be further improved (1) by the inclusion of FDG-PET results in the methodology of response/progression evaluation and (2) for response/progression evaluation in clinical trials with targeted agents.
- Standardized definition of time to event endpoints for cancer clinical trials (DATECAN), with current focus on pancreatic cancer and sarcomas (presented at ASCO 2012).
- A study of surrogacy in patients with T3-4 rectal cancer treated with preoperative radiotherapy with or without chemotherapy (Eur J Cancer 2012; doi:10.1016/j.ejca.2012.03.016).
- A study of the value of whole body MRI for the diagnostic of metastases in prostate cancer with researchers from Université Catholique de Louvain (Eur Urol 2012;62(1):68-75).
- The statistics department is also supporting the design of studies assessing new imaging techniques in the QuIC-Concept project (Innovative Medical Initiative (IMI))
- Methodological research on reporting of quality of life data together with other members of the Quality of Life Department continues (minimum clinically meaningful differences, Ann Oncol 2011;22(9):2107-2112, and quality of life prognostic factor for survival, J Nat Cancer Inst 2011;103 (24):1851-1858).
- The collaboration of the statistics department with the University of Liege on methods for the analysis of ordinal longitudinal data in the presence of missing data (multiple imputation techniques, publication submitted) and for the testing of the proportional odds assumption is

also progressing. A comparison of the results when analyzing QoL data with these methods or as continuous data is foreseen. A PhD thesis on the topics by Anne –Françoise Donneau, ULg should be submitted by the end of the year.

- A PhD thesis (C. Coens) on missing data in HRQoL studies was initiated in March 2011. This work involves collaboration with both psycho-oncology and statistical experts from the AMC institute in Amsterdam. So far, this has resulted in an oral presentation on the use of divergent imputation at the ISOQOL 2011 conference.
- A PhD thesis (T. Gorlia) on the diagnosis and prognosis of brain tumors is nearing completion and continues to produce interesting results including a pooled analysis in recurrent glioblastomas (Grade IV) (Eur J Cancer 2012;48(8):1176-1184) which identified new prognostic factors and presents new prognostic models, a pooled prognostic factor analysis and prognosis modeling in low grade gliomas (Grade II), and a project jointly developed with US cooperative groups. A prognostic factors analysis of EORTC trial 26951 to identify important prognostic factors and develop prognostic models for anaplastic gliomas (Grade III) is ongoing.

IT Department

The IT Department is responsible for the development of software and systems used to manage cancer clinical trials. VISTA TRIALS is the Clinical Data Management System (CDMS) developed by the IT Department and used to run all clinical data activities at EORTC Headquarters. VISTA TRIALS is a suite of applications ranging from double data entry, database definition, up to the SAS export module, including ORTA, the web-based patient registration and randomization tool. Satellite applications are linked to VISTA TRIALS, such as the Regulatory system or the Contract Management Tool (CMT). VISTA TRIALS is a community trademark owned by the EORTC. The source code of VISTA TRIALS is registered for Intellectual Property as an I-Depot.

The EORTC Imaging Platform provides all EORTC centers with an easy upload portal, which allows them to transmit a patient's images in a secured and protected way. The reviewing functionalities are powered by VISIO+, the Keosys viewer. Collected images are stored centrally and linked to the patient's clinical data. The central review can be performed from any Internet workstation and does not require software installation.

In 2011 the EORTC became a Platinum Member of CDISC (Clinical Data Interchange Standards Consortium). The CDISC standards are being implemented in the new version of VISTA TRIALS. This new version complies with the CDISC principles, is built around the CDISC domains and visits, and will allow for easier collaboration with external partners such as academic groups, CRO's or industry, providing a smooth way of exchanging clinical data. The "visit" model in the Remote Data Capture module will help the investigator with the form flow. Through the implementation of CDISC standards, as well as the ongoing debriefing of the experiences of our sites with VISTA, transparency and ease of data collection will be improved both at the investigational site and at EORTC Headquarters. This strong effort to optimize our database systems further enables the EORTC to perform today's complex clinical trials.

Thanks to the latest upgrade of the ORTA system along with the minimization technique, the EORTC can now run both randomization in blocks and by minimization method.

Documentation is important for clinical trials. In this area, EORTC HQ is adopting new standards. The Drug Information Association (DIA) Reference Model is now being implemented for all new trials. The EORTC e-TMF (electronic Trial Master File) is built upon the Microsoft Sharepoint platform.

The new CTMS (Clinical Trials Management System – PRISMA) will help in managing the study data (centers, investigators, study milestones, et cetera). It is designed to provide global overview on all projects but also very details information about a specific protocol. The software developed at EORTC Headquarters follows a standard System Development Life Cycle (SDLC) in order to comply with the regulations of the US FDA (United States Food and Drug Administration), 21-CFR part 11 (electronic records - electronic signature).

In order to improve system availability and fault tolerance while reducing maintenance and running costs, the system infrastructure has been rebuilt around virtualization technology. Most servers at EORTC Headquarters are now running on a virtual platform and are ready for migration to cloud computing.

Data Management Department

The main goal of the Data Management Department is to ensure adequacy, integrity, and quality of the patients' data that are used to answer the questions of our studies.

The Data Management Department is composed of 27 full time data managers led by four lead data managers, one associate Head of Department, and one Head of Department. Two data entry clerks encode the data that is still submitted on paper case report forms (CRFs), and one administrative assistant lends support to the whole department.

In 2011, 310000 forms from among 93 studies were validated by the Data Management Department.

Clinical Data Management System

The clinical data management system, VISTA TRIALS, is used to store and manage data from clinical studies and is an essential tool for data management. This system, developed by the EORTC, is the result of a fruitful collaboration between the IT and Data Management Departments, who interact on an ongoing basis to innovate and improve it.

In order to comply with regulatory requirements and continually improve procedures that facilitate cooperation with pharmaceutical industry partners, the EORTC has recently upgraded its already 21 CFR part 11 compliant clinical data management system to CDISC standards.

VISTA Trials integrates several applications that will be upgraded over the coming months, among which is the VISTA Remote Data Capture system (VISTA RDC) that is used in all of our new trials since 2009.

Data Management processes

Several data management procedures ensure that the goals of the Data Management Department are achieved. Some of the key processes are:

1. CRF development

CRFs (electronic or paper) are the most important tool of a clinical study besides the protocol. EORTC procedures require the design of CRFs to start in parallel with protocol development to

ensure compatibility of both instruments. CRFs are built using a series of templates that are currently under revision.

The process of CRF development was designed to guarantee that the right data is collected in the right way to make possible a meaningful analysis of the study's outcome. CRF design is a collaborative effort which requires not only the expertise of the data manager, statistician, and clinical research physician involved in the study, but also that of translational researchers, physicists, as well as other specialists depending on the setting of the given study. The study coordinator plays an important role in the design of the CRF as do the study nurses, whose expertise is very much appreciated in making the layout of the CRFs as comprehensive as possible from the perspective of the site.

2. Data review and validation

Data collected through electronic CRFs undergo a validation process ensuring their completeness, consistency, and reliability.

The main data review is performed by the Data Manager, who uses several computer tools to perform edit and validation checks. Since this critical review requires a comprehensive understanding of the data, the EORTC only employs Data Managers who have a strong scientific background.

Another aspect of data validation is reconciliation of serious adverse events (SAE). This step ensures the consistency between the SAE information stored in both the safety database (managed by the EORTC Pharmacovigilance Unit) and in the clinical database (managed by the Data Management Department). This reconciliation is also a collaborative effort which involves the data manager, the pharmacovigilance manager, and also the clinical research physician.

Medical review is another important step of the data validation in which the study coordinator, clinical research physician, and data manager together review specific aspects of the patient's files to ensure appropriate medical input is brought to the data. Topics requiring medical advice include but are not limited to: patient eligibility, compliance with protocol prescribed treatment, evaluation of response, and safety evaluation.

Quality Assurance and Control Unit

The Quality Assurance and Control Unit (QA&C) unit promotes and encourages quality awareness throughout the organization and provides expertise in the development and maintenance of the quality management system pertaining to clinical study activities.

The QA&C team contributes to minimizing the risk of non-compliance, coordinates internal and external audit programs, performs on-site monitoring visits, and provides the necessary training and assistance to achieve these goals.

Site monitoring

The EORTC strategy is to perform on-site monitoring in studies having a high or medium level of risk and/or when required by pharmaceutical industry partners. At the study level, the frequency and distribution of site visits across participating institutions depends on the accrual and the observations reported by the clinical research assistant(s) (CRA) during site visits and/or by the EORTC data managers during data cleaning.

The aim of site monitoring is to assess data quality and compliance with ICH-GCP and protocol. This is achieved through direct source data verification by the CRAs.

Monitoring Visits	2002 - 2011	2011
Trials	43	12
EORTC Groups	12	7
Institutions	233	41
Total Site Visits	3892	127

Site audits

A yearly audit program allows routine audits in a selection of EORTC sites based on risk criteria: quality issues, delay in data submission, big recruiting sites participating in non-monitored studies.

Additional audits are also conducted for the new institutions entering the EORTC network (audit is conducted after the first patient enrolled) and for the institutions flagged as 'quality exclusion' for which a qualification visit by QA&C is mandatory to be re-integrated into new EORTC trials.

In addition, the EORTC conducted contract research organization (CRO) audits.

From January 2011 until June 2012, the QA&C performed 16 external audits and coordinated two audits and inspections of the EORTC Headquarters by a third party.

Audits	2002 - 2011	2011
Trials	68	6
EORTC Groups	15	5
Institutions	118	4
Contract Research Organizations (CRO)	7	1
Total Audits*	217	7

** Trial-related audits*

Audits and inspections of EORTC Headquarters

In 2011, the EORTC Headquarters had a mock US Food and Drug Administration inspection upon the request of GlaxoSmithKline in the context of the preparation of a regulatory submission for Pazopanib in Sarcomas.

In 2012, the EORTC had a GCP routine inspection conducted by the Belgian Competent Authorities (Federal Agency for Medicines and Health Products) in cooperation with Swissmedic and the Danish Medicines Agency, in the framework of the Pharmaceutical Inspection Convention / Pharmaceutical Inspection Co-operation Scheme (PIS/C) GCP exchange group.

Data Timeliness

The QA&C unit is responsible for identifying and tracking sites with persistent missing data by means of a central Data Timeliness (DTL) procedure conducted on an annual basis. This process is in addition to the standard tri-monthly form request performed by the EORTC Data Management Department.

Following the Data Timeliness procedure performed in 2011 on 20 trials, 24 EORTC sites (7% of all recruiting sites) received a warning from EORTC Headquarters for non-compliance with regards to data submission, and three of these were temporarily suspended for further registration. Additionally, 79 non-EORTC sites (representing 13% of all recruiting sites) were non-compliant.

In 2012, the Data Timeliness procedure will apply to 30 trials.

Training and Quality management system

The QA&C coordinates the development and review of EORTC Headquarters procedures and participates in the organization of related training courses. Furthermore, the unit provided help to the various EORTC units and departments in order to harmonize trainings and training documentation; the training plan for new employees at EORTC Headquarters are now centralized at QA&C. The GCP course for investigators in collaboration with EFGCP (European Forum for Good Clinical Practice) was also organized by EORTC Headquarters in 2011.

Contracts, Accounting and Finances Reporting Unit

The main responsibilities of the Accounting and Financing Reporting office are to:

- ensure that accounting records are accurate and prepared in time and in accordance with internal and external requirements;
- coordinate and organize the consolidated accounting audit carried out by Ernst & Young;
- ensure statutory reporting and fiscal requirements.

The main responsibilities of the Budget and Contract office are:

In collaboration with other EORTC units:

- initiate and update agreement templates;
- initiate discussions concerning the development of study- or project specific agreements and their amendment, as needed;
- negotiate and correctly manage study or project specific agreements with third party(ies) in a timely fashion while respecting the integrity of the EORTC.

In collaboration with Accounting and Finances Reporting office:

- handle all study-related budgets and quarterly invoicing of third party(ies);
- estimate and analyze the budget and income of EORTC Headquarters;
- participate in the conduct of the financial audit.

Human Resources Unit

As of October 2012, the EORTC Headquarters staff consisted of 169 members (110 females, 59 males representing 20 different nationalities) of which 152 are full-time and 17 part-time employees and include then research fellows, three interim staff, and two consultants.

Clinical Trials Insurance Office

Provision for insurance or indemnity to cover the liability of the investigator and/or the sponsor is often an absolute requirement before an ethics committee considers giving its favorable opinion to proceed with a trial. The EORTC, as an academic sponsor, has a fully compliant clinical trial insurance package which takes into account all national and international requirements and parameters.

Education Office

The EORTC Education Office organizes and manages all aspects of EORTC courses and conferences. Prior to the course this support involves, among other tasks, preparation of educational materials (printed materials etc.) and on site logistical arrangements, application for accreditation of the course, and registration of course participants. During the event the Education Office manages the set up at the course venue and ensures smooth operation of the event. Following the event the Education Office handles the review of course evaluation forms, distributes continuing medical education credits (CMEs) to the participants, and oversees the handling of invoices.

Courses which the Education organized in 2011 – 2012 include "Clinical Trial Statistics for Non-Statisticians", "One-Day Introduction to EORTC Trials", "Methodology of Cancer Clinical Trials: The Next Generation", and "Organization and Implementation of Cancer Clinical Trials". In collaboration with the EORTC Director General's Office and Communications Office, the Education Office also organizes EORTC conferences including "EGAM" (EORTC Groups Annual Meeting), "Markers in Cancer", a joint meeting by the EORTC, the American Society for Clinical Oncology (ASCO), and the United States National Cancer Institute (NCI), and the EORTC 50th Anniversary Conference held in March 2012. (Please see pages xx-yy for further information about these courses and conferences.)

Communications Office

The EORTC Communications Office plays an integral role in conveying information about EORTC activities both internally, within the EORTC Network, as well as externally to the various European cancer leagues, the scientific community, the pharmaceutical industry, patients, and the public. Through these efforts, the Communications Office aims to increase the visibility of EORTC research activities and raise public and media awareness of the importance of cancer clinical research in Europe.

Information about EORTC activities is shared on an ongoing basis in a number of ways, notably through the organization of events in collaboration with the Director General's and Education Offices, writing and producing printed materials, press releases, articles for journals specializing in the analysis of issues affecting the general public, newsletters, and the EORTC website.

Conferences and events organized by the Communications Office in collaboration with the Director General's and Education Offices include EGAM (EORTC Groups Annual Meeting) and Markers in Cancer, A joint meeting by the EORTC, ASCO (American Society for Clinical Oncology), and the NCI (United States National Cancer Institute). Organization of meetings of this scale involves conducting planning meetings, arranging for sponsorship, advertising, as well as managing the associated logistics of hosting an event at a convention center. The Communications Office was very

involved in the organization of the recent EORTC 50th Anniversary Conference, and also played a central role in the production of the special European Journal of Cancer Supplement: EORTC 1962 – 2012: 50 Years of Progress Against Cancer, Eur J Cancer 2012;10(1):1-166.

In addition, an EORTC Information Booth is maintained at several major international cancer conferences including ASCO, EORTC-NCI-AACR and ECCO-ESMO. Posters for presentation at scientific conferences are also produced by this office (32 posters produced in the 2012*). Recently, the Communications office organized a special EORTC-IMI (Innovative Medicine Initiative) symposium at the 24th EORTC-NCI-AACR (American Association for Cancer Research) symposium. This symposium, Reducing attrition rates in anticancer drug discovery and development: IMI approaches, was designed to highlight the efforts of three IMI projects focused on cancer. Among these is QuIC-ConCePT (Quantitative Imaging in Cancer: Connecting Cellular Processes with Therapy), a project managed by the EORTC and which aims to provide drug developers with imaging biomarkers that can show earlier and more accurately how patients' tumors respond to drugs in cancer clinical trials. The Communications Office also manages the website for the QuIC-ConCePT project: www.quic-concept.eu.

The EORTC website is a critical tool for communication within the EORTC Network as well as for external communication to professional communities and the lay public. Communications Office efforts over the course of 2011 and 2012 led to a redesigned EORTC website which has been online since March 2012. The tab bar enables quick access to information over the EORTC Network, Headquarters, Research Group webpages (managed by the Communications Office with the assistance of the relevant EORTC Headquarters teams), clinical trials, a section dedicated to information of interest to patients, and listing of EORTC partnerships, and a listing of conferences and courses is located on the homepage. The Communications Office remains active in further developing and utilizing this medium.

Press releases are drafted for use by external media, and following the embargo these are then posted on the website. In 2011 through the first half of 2012 the following press releases were generated:

- Results of EORTC Gynecological Cancer Group trial 55955 / MRC OV05 with the United Kingdom Medical Research Council;
- Results of EORTC Soft Tissue and Bone Sarcoma Group trial 62072 PALETTE with Glaxo SmithKline;
- Results of EORTC Melanoma Group trial 18991 with Merck;
- International Rare Cancers Initiative EORTC-UK-US Global Collaboration;
- Completion of recruitment for MINDACT with BIG and Agendia;
- Clinical Practice Guidelines on the management of Hepatocellular Carcinoma;
- CDISC and EORTC: implementing standards for cancer clinical trials in Europe;
- EORTC & Alliance Boots join forces to support pan-European cancer research in advanced colorectal cancer;
- Results of EORTC Gynecological Cancer Group trial 55041;
- Results of EORTC Brain Tumor Group trial 26951;
- EORTC Enters Agreement with Imaging Biometrics for Advanced Imaging Trials.

In addition to Press Releases, the Communications office writes research updates and highlights which are posted on the website, and News Alerts are regularly sent to the EORTC membership,

cancer leagues, and other partners on a regular basis. A bibliography database of EORTC publications is also maintained on the website, and plans are in place to have DOI (digital object identifier) links added to these references so that users can gain fluid access to these materials.

Printed materials produced by the Communications Office include brochures, press and patient packs, the EORTC Annual Report, advertisements, etc. Efforts are currently underway to translate the newest patient information brochure "Clinical Trials: all you need to know" into additional languages. The Communications Office assists other EORTC Headquarters Departments in the writing and editing of documents, reports, policies, memorandums of understanding, and communications.

The Communications Office wrote several articles in 2011 through the first half of 2012 targeted at informing the general public of EORTC activities. These included articles in Clinical Investigation, Public Service Review: European Union Issue, Science Connections, Revue Onco, Touch Briefings, European Oncology and Haematology, Public Service Review EU Science and Technology, MAPI Newsletter, Eusoma Newsletter, Experimental Review of Pharmacoeconomics & Outcomes Research covering a wide range of topics such as biobanking, international investigator clinical trials, highlights of EORTC research over 50 years, and advances in cancer treatment.

(Ten for ASCO, 21 for EORTC 50th Anniversary, eight for ISOQOL, and one each for EAU, ESTRO, EPICLIN.)*

Director General's Office

The EORTC Director General's Office (DGO) is involved in all tasks in support of the EORTC Director General. The DGO also assists in the management and organization of meetings with:

- EORTC President, Board, General Assembly, and Scientific Audit Committee;
- Cancer leagues, foundations and donors;
- Belgian Ministries and EU Commission;
- EORTC Charitable Trust;
- Insurance;
- Legal matters (Moniteur Belge).

In 2011 – 2012 the DGO organized in collaboration with the EORTC Education and Communications Offices several EORTC conferences including EGAM (EORTC Groups Annual Meeting), "Markers in Cancer", a joint meeting by the EORTC, the American Society for Clinical Oncology (ASCO), and the United States National Cancer Institute (NCI), and the EORTC 50th Anniversary Conference held in March 2012. The DGO was also instrumental in the organization of the 24th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics.

Liaisons with internal EORTC Headquarters Departments, Offices, Units, and the EORTC Headquarters Coordinating Committee (HQCC) are also under the purview of the DGO.

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Courses & Conferences

The EORTC Headquarters staff members are involved in the organization and teaching of the following courses and meetings:

EORTC Courses in 2012

Clinical Trial Statistics for non-Statisticians (Brussels, Belgium, 12-15 June)

This course is designed as an introduction to the statistical principles which form the basis for the design and analysis of cancer clinical trials. It will concentrate on the philosophy and understanding of the statistical principles that are used on a day-to-day basis in conducting clinical trials and will not simply present statistical formulae in a cookbook fashion. This course is aimed at non statisticians (medical doctors, data managers, etc.) who are already working in the field of clinical trials and who have had an introductory course in statistics, or at statisticians with little or no experience in clinical trials. For those persons who would like a review of the basic statistical concepts, an optional half day introduction to statistical methods has been organized.

One-Day Introduction to EORTC Trials (Brussels, Belgium, 14 September)

This course is dedicated to newly participating members (investigators, data managers, research nurses, etc.), and industry representatives. The purpose of this introductory course is to give general information on the strategies and principles for collaboration with EORTC. Additionally, participants will receive information about the functioning of the EORTC and about Trials methodology, investigator / site quality requirements and control, patient safety management, adequate data collection and pitfalls for reliable data. Furthermore you will be shown our on-line registration / randomization process and remote data capture system.

Methodology of Cancer Clinical Trials: The Next Generation (Brussels, Belgium, 11-14 December)

This course is designed at an advanced level for medical doctors, specialists in oncology, and cancer clinical research professionals. The course will focus on the new aspects and methodological challenges of modern cancer clinical trials. The course will address new clinical trials features aimed at understanding the biology of the disease and document molecular determinants, whether host or disease related, which may be prognostic or predictive of patient outcome. As innovative approaches will be discussed, attendees are expected to already have a good understanding of the basis of clinical trial methodology.

EORTC Courses in 2013

Clinical Trial Statistics for non-Statisticians (Brussels, Belgium, Spring)

See the description above.

One-Day Introduction to EORTC Trials (Brussels, Belgium, Fall)

See the description on page 186.

Organisation and Implementation of Cancer Clinical Trials (Leuven, Belgium, Fall)

This course is designed to Clinical Research Coordinators (Data Managers, Project Managers, Research Nurses, Radiation Technologists, etc.), with the aim to stimulate, improve and expand the collaboration; develop the different skills, roles and knowledge of those working within the clinical research environment. Participation in the course will therefore have a positive impact upon quality and management of clinical trials.

EORTC Meetings in 2012

EORTC: Celebrating 50 years of Progress Against Cancer (Brussels, Belgium, 15-16 March)

The EORTC will celebrate Fifty Years of Progress Against Cancer on 15-16 March 2012 at the Square Brussels Meeting Centre, Mont des Arts, 1000 Brussels. The EORTC is delighted to host this conference promoting Pan-European cancer research for the benefit of all cancer patients and look forward to you joining us in Brussels to mark this occasion.

3rd EORTC Quality of Life, Symptom Research and Patient Reported Outcomes in Cancer Clinical Trials Conference (Brussels, Belgium, 17-19 October 2012)

This conference will examine the importance of using a patient's perception and experience, when undergoing new and pioneering clinical trials, in developing novel treatments to help reduce the burden of cancer and perhaps even cure it. This conference aims to cover a broad range of topics in HRQOL, symptom research and cancer clinical trials. It will address recent developments of EORTC tools, as well as other developments and research in oncology.

EORTC Meetings in 2013

EORTC Groups Annual Meeting, EGAM (Brussels, Belgium, 7-8 March)

This meeting of all clinical and translational EORTC groups presents the opportunity to all participants to contribute to the scientific activities of the EORTC, irrespective of their primary group affiliations, in order to maximize cross expertise in a transversal setting.

International Courses and Conferences involving the EORTC (2012-2013)

8th European Breast Cancer Conference (Vienna, Austria, 21-24 March 2012)

As part of a biennial series of pioneering meetings, the eighth European Breast Cancer Conference (EBCC-8) is devoted to presenting, educating on, and debating the most up-to-date developments, topics and ideas within the field of breast cancer. The Conference goals are: to continue advancing the rapid translation of clinical research into practice, to encourage the integration and coordinated organization of treatment modalities, and to bring together patient representatives, clinicians, health professionals and scientists to continue working together towards delivering equal access and optimal care for breast cancer patients.

1st Gallen EORTC Gastrointestinal Cancer Conference: Primary Therapy of Early GI Cancer with International Treatment Consensus (St Gallen, Switzerland, 22-24 March 2012)

This new bi-annual conference will focus on primary therapy of early, potentially curable cancers of the gastrointestinal tract. Experts actively engaged in basic and clinical research as well as clinical management of gastro-intestinal cancers will present their latest data, critically reviewed by leading specialists in the field. Join a conference with a new international consensus attempt: Differential approach to the gastro-esophogeal cancers – public interactive panel discussion and vote.

Methods in Clinical Cancer Research (FLIMS) (Waldhaus, Switzerland, 23-29 June 2012)

The ECCO-AACR-EORTC-ESMO Workshop on Methods in Clinical Cancer Research, or the 'Flims Workshop' in short, is an educational program that introduces junior clinical oncologists in any oncology subspecialty to the principles of good clinical trial design. Since 1999, this annual workshop has been held in the last full week of June, hosted by the small town of Flims in Switzerland. The organizers pursue the ultimate goal of developing a cadre of well-trained, experienced researchers whose expertise will foster better clinical trial designs and thereby hasten the introduction of improved regimens for cancer therapy and prevention into everyday medical practice and patient care.

Markers in Cancer 2012: A Joint Meeting by ASCO, EORTC and NCI (Hollywood, Florida, 11-13 October 2012)

The Markers in Cancer 2012 meeting (formerly known as the ASCO-NCI-EORTC Annual Meeting on Molecular Markers in Cancer) will stimulate discussion on the use of biomarkers as a tool for screening, diagnosis and treatment of cancer. Designed for clinicians, pathologists, laboratory scientists, statisticians, and others who specialize in molecular diagnostics, the meeting will present the latest advances in cancer markers to assess drug efficacy, improve prognostic and predictive evaluations and imaging, and enhance clinical trial development. Bookmark markersincancer.org for meeting updates.

EORTC - NCI - AACR International Conference on Molecular Targets in Cancer Therapeutics (Dublin, Ireland, 06 - 09 November 2012)

This symposium will bring together academics and scientists and representatives from the pharmaceutical industry to discuss innovations in drug development, target selection and the impact of new discoveries in molecular biology. This symposium will be organized to ensure the maximum amount of interaction and discussion through an exciting range of plenary sessions and lively workshops.

EORTC-EANO-ESMO: TRENDS IN CENTRAL NERVOUS SYSTEM MALIGNANCIES (Prague, Czech Republic, 22-23 March 2013)

The main focus of the joint EORTC-EANO-ESMO Conference is to improve the neuro-oncology field, accelerate the translation of cutting edge discovery at the clinical level, and further promote international scientific cooperation, debate and exchange.

Markers in Cancer 2013: A Joint Meeting by ASCO, EORTC and NCI (Brussels, Belgium, 7-9November 2013)

See the description on page 188.

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EORTC Directory

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