



Academic Cancer Research

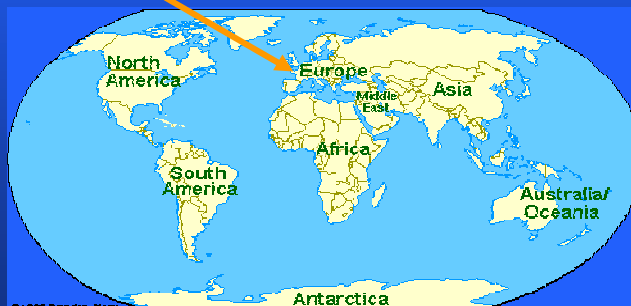
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EORTC

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CANCER WORLDWIDE AND IN THE EUROPE

EUROPE 1.498.000 new cases
975.000 deaths



5.800.000
new cases
diagnosed
worldwide
in the year
2002

Adapted from GLOBOCAN 2002



LONG TERM SURVIVAL (%)

	1970	2005
• Leukaemia in children	0	80
• Leukaemia in adults	0	45
• Bone cancer	5	60
• Advanced testis cancer	0	95
• Breast cancer	40	85
• Non-small cell lung cancer	0	20
• Colon cancer	30	60
• Hodgkin's disease	10	85

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Brief History of Cancer

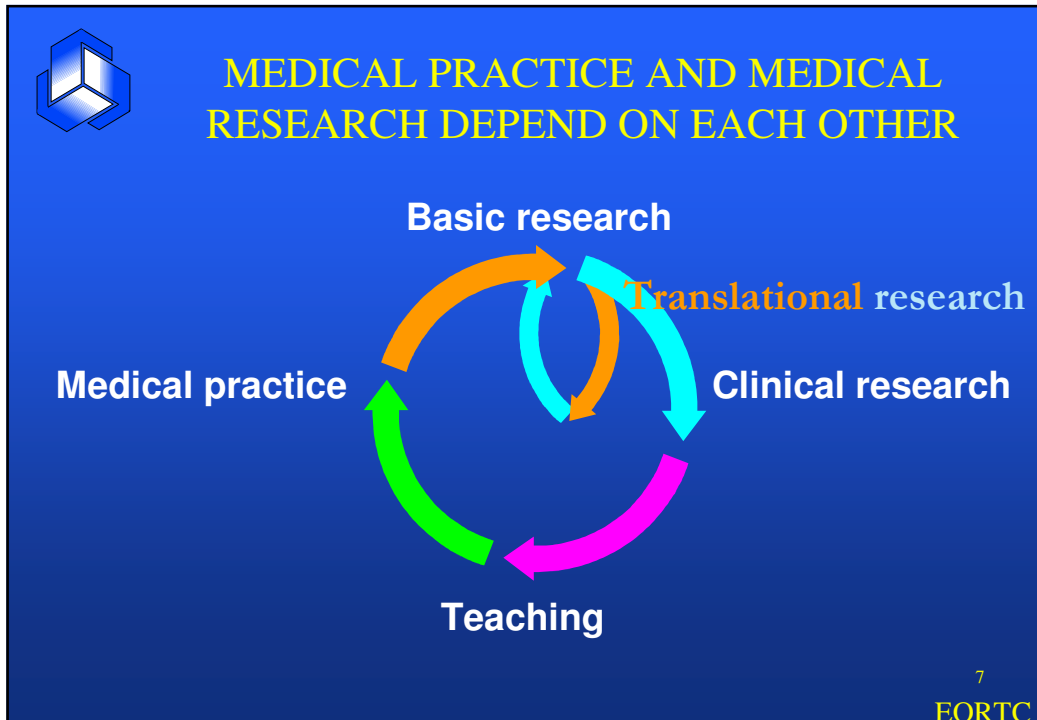
- Cancer has replaced heart disease as the leading cause of deaths for people under 85 years of age
- Continued emphasis on prevention, early detection and improved treatment strategies
- People are living longer and better after diagnosis -- New emphasis on quality of life and long-term cancer survivorship issues (chronic disease model)
- **Research has helped to improve cure rates, earlier diagnosis, quality of life and find less toxic treatments for many types of cancer**

Importance of Cancer Research

- Management of cancer improves by small (but important) steps - only through high quality clinical trials can we improve outcome
- Several studies have shown that patients treated on clinical trials have better outcome:
 - 26 comparisons of outcome of cancer patients enrolled and not enrolled in clinical trials (Peppercorn J, Lancet 2004): **suggested that trial patients did better. No studies recorded worse outcome in trial-enrolled patients than in non-trial patients**

Clinical Trials: One Key to New Discoveries

- Phase I: what is best way to give a treatment and what should the dosage be?
- Phase II: does the new treatment have a positive effect against a specific type of cancer?
- Phase III: How does the new treatment compare with the best existing treatment?
- **Regulatory (EMEA, FDA) Approval**
- **Introduction in routine medical practice**



-
- The diagram illustrates the interconnectedness of medical practice, research, and teaching. It features a central cycle of four colored arrows forming a circle. The arrows are labeled as follows: a blue arrow at the top labeled 'Basic research', a red arrow on the right labeled 'Clinical research', a green arrow at the bottom labeled 'Teaching', and a yellow arrow on the left labeled 'Medical practice'. A smaller red arrow labeled 'Translational research' is positioned between the 'Basic research' and 'Clinical research' arrows, indicating the flow of knowledge from basic to clinical research. The entire diagram is set against a dark blue background with a white cube icon in the top left corner.
- Clinical Research is Essential To:**
- Translate new discoveries into clinical practice
 - Define state-of-the-art treatment
 - Identify ineffective and/or redundant treatments
 - Guarantee best medical practice
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Advantages and Importance of Large Scale Multi-National Trials

- In common and devastating malignancies where even a small improvement in survival will have a major impact on public health
- In rare tumors where multinational effort is necessary to reach required sample size
- Discourage national/small sized trials that are inconclusive, unethical and concomitantly conducted in several countries

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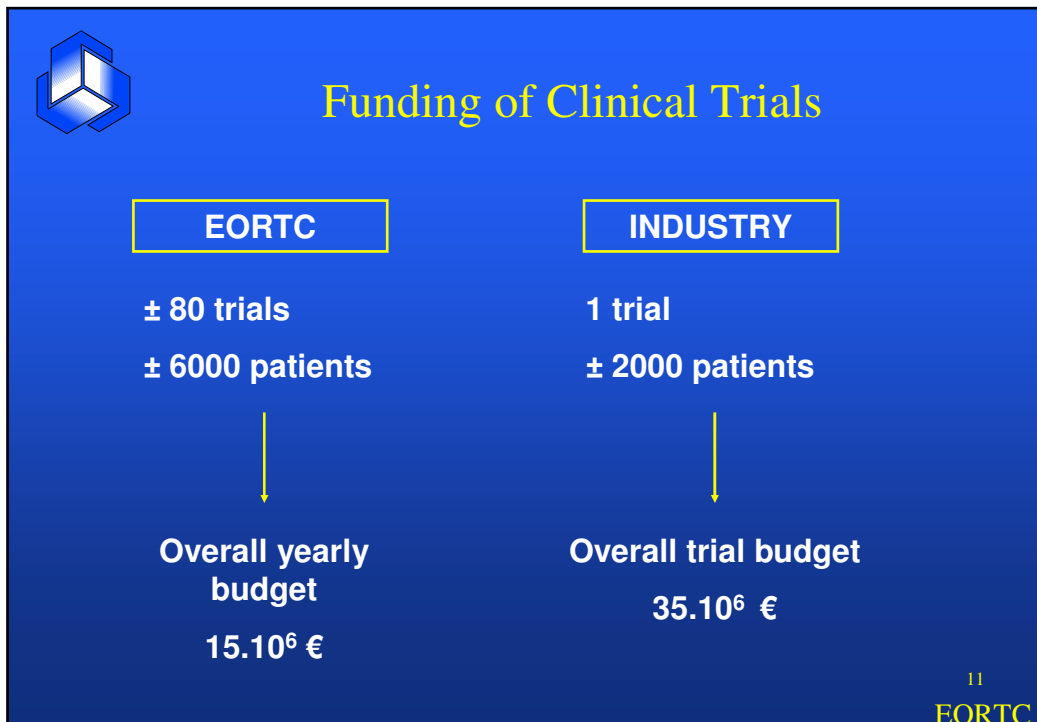


The Importance of Academic Cancer Clinical Research

- Independent objective evaluation
- Focusing on clinically important questions
- Performing all types of cancer clinical trials: screening, prevention, diagnostic, quality of life, not only treatment trials
- Large scale trials, needed to change practice and establish state-of-the-art treatment
- Multidisciplinary strategies in oncology
- To test new concepts and develop new strategies that are:
 - Part of a strategy to improve patient care
 - May not be to the direct / immediate benefit of the pharmaceutical industry
- Tissue banking

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Why Collaboration in Academic International Clinical Trials is Important for Small or Less Develop Countries ?

- For patients: Access to the highest quality of care
- For health professionals: training, discipline, improving overall quality of work
- Improving national cancer care
- Improving the quality of scientific research



European Organization for Research and Treatment of Cancer (EORTC)

- Private and not for profit organization
- **Main mission:** promote and conduct research to improve cancer care
 - **Core activity:** conduct clinical trials
 - ◆ **International**
 - ◆ **Multidisciplinary**
 - ◆ **Develop new treatment strategies**
 - ◆ **Define new standards of care**
 - ◆ **Large academic trials**

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Accrual of patients in EORTC clinical studies in 2005: 4387 patients

European Union

Austria: 30
Belgium: 516
Cyprus: 17
Czech Republic: 6
Denmark: 62
Finland: 5
France: 788
Germany: 292
Hungary: 15
Rep. of Ireland: 6
Italy: 425
Latvia: 2
Luxemburg: 1
Poland: 135
Portugal: 77
Slovak Republic: 69

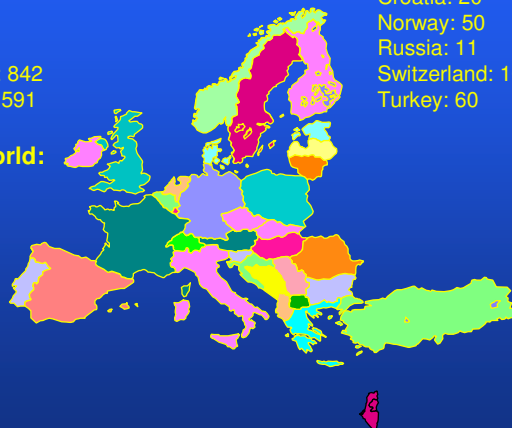
Slovenia: 48
Spain: 82
Sweden: 17
The Netherlands: 842
United Kingdom: 591

Rest of the World:

Australia: 2
Egypt: 41
Israel: 20
Lebanon: 11
Mexico: 1
Peru: 31
South Africa: 4
U.A. Emirates: 1

Non-EU Countries:

Croatia: 20
Norway: 50
Russia: 11
Switzerland: 109
Turkey: 60



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EORTC Achievements

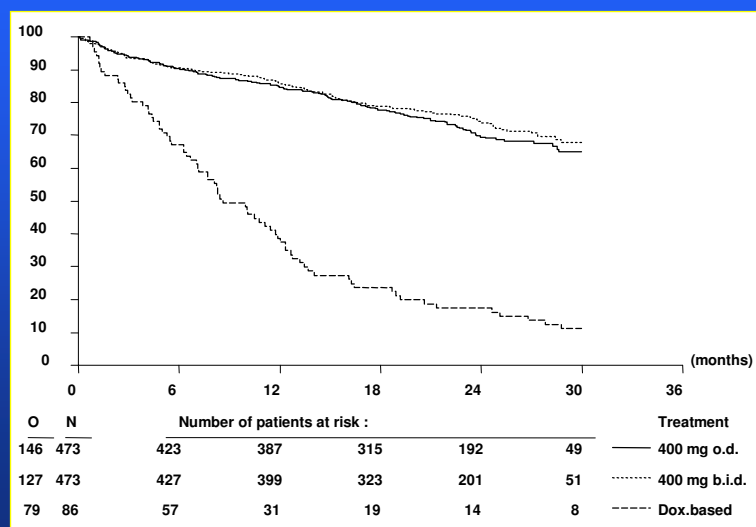
- Through the conduct of large scale randomized phase 3 trials and meta-analyses, EORTC studies have had a major impact on establishing new standards of patient care.
- **These results benefit not only in patients in Europe, but also patients worldwide.**
- **Recent examples of major EORTC trials leading to change practice**
 - **Head & Neck cancer**
Concomitant cisplatin and radiotherapy post surgery
New England Journal of Medicine, May 2004
 - **Glioblastoma**
Temozolomide with radiotherapy as adjuvant treatment
ASCO, Plenary Session 2004
 - **GIST**
Role of Glivec
The Lancet, September 2004

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Glivec Study in GIST Overall survival



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The Lancet Sept. 2004

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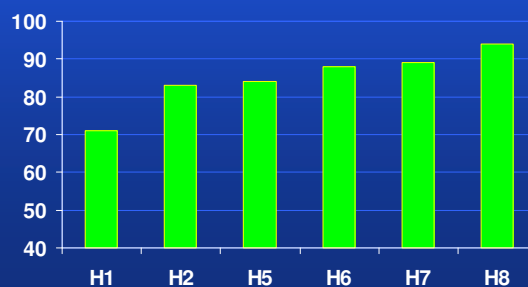
Three time periods in the treatment of Hodgkin's lymphoma

1965-1985: **disease** oriented: **cure**

1985-1995: **treatment** oriented: **uncomplicated cure**

1995-present: **patient** oriented: **risk adaptation, QoL**

Survival in 6 consecutive EORTC-trials on Hodgkin's lymphoma



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CENTRAL AND EAST EUROPEAN ONCOLOGY GROUP

1983: South and East European Oncology Group (SEEOG);

1988: Central and East European Oncology Group (CEEOG);

Scientific activity: 15 phase II and III trials, 4100 patients, 12 countries, 36 centres





Challenges for Future Academic Clinical Research in Europe

- Heavy procedures in Europe to activate clinical trials
- High regulatory burden
- Increased costs by 85% - 120%
- Varying national implementation of the EU Directive 2001/20/EC
- Increased difficulties to organize trials with new EU territories

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CANCER CLINICAL TRIALS : THE LEGAL CONTEXT NEW E.U. DIRECTIVE ON CLINICAL TRIALS



- To promote multinational clinical trials in Europe
- To harmonise clinical trials procedures
- To reinforce patients protection

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CHALLENGES OF THE LEGAL FRAMEWORK


Exponential increase in...

- Costs of clinical trials
- Complexity and workload for study activation
- Delays in study activation (4 to 11 months)
- Workload for handling SUSARS

...

?

- ↑ quality of clinical trials and patients protection
- Provide an harmonized frame for their conduct



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Threats for Academic Research

- Increased bureaucratic and administrative workload
- Pressure from regulatory authorities
- Financial constrains
- Lack of independent funding

→ loss of interest

- Uncontrolled research with tumor material

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Challenges for Cancer Clinical Research in Europe

- Need to update and harmonize rules for clinical trials in Europe
- 2 types of clinical trials
 - drug development
 - therapeutic strategies: multidisciplinary approach
- To promote independence of investigators by increasing funding for strategy trials which will protect the academic research and clinical science as well as the patients

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LOOKING TOWARDS THE 21ST CENTURY

- Cost containment is a major threat in restructuring oncology practice
- Less than 5% of cancer patients benefit from clinical trials because of lack of access to the trials methodologies in most hospitals
- Need to redefine the physician-patient dialogue in this information age.

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