Academic Research in Europe

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Type of clinical trials

Type 1: Designed and sponsored by the Pharmaceutical Industry, proposed to the Investigator and accepted

Type 2: Designed and sponsored by the Investigator, proposed to the Pharmaceutical Industry and accepted

Type 3: Designed and sponsored by the Investigator, not supported by the Pharmaceutical Industry
Investigator sponsored clinical trials

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Type 3: Designed and sponsored by the Investigator, not supported by the Pharmaceutical Industry

Truly non commercial Academic Trials
Is the academic research necessary?
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EORTC (2001)

“The 40% of the studies that have changed the management of Cancer in the last 40 years have been sponsored by the Academy”
Is the academic research necessary?
YES!: there is a need to respond to “less” attractive questions for the pharmaceutical industry.

- “head to head” of already approved treatment options
- Optimal duration of treatment
- Studies needing a Long-term follow-up (adjuvant)
- No drug-driven studies
YES!: There is a need to respond to “less” attractive questions for the pharmaceutical industry.

- “Head to head” of already approved treatment options
- Optimal duration of treatment
- Studies needing a Long-term follow-up (adjuvant)
- No drug-driven studies

YES!: Need of high and quick recruitments of patients in clinical trials in cancer.
Clinical trials
Clinical trials
Clinical trials
Clinical trials
Clinical trials
In the file.
EU directive seems to be created thinking only on registration of new compounds and pharmaceutical industry research
Academic clinical research issues

Requirements

Resources
How to address these costs?

- Public resources
- Charities
- Private sector (pharma industry)
How to address these costs?

<table>
<thead>
<tr>
<th>Country</th>
<th>Charities</th>
<th>Public</th>
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<td>Germany</td>
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<tr>
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<tr>
<td>UK</td>
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</tbody>
</table>

How to address these costs?


Consulta de páginas webs en Octubre 2012:

Webs pages:

https://www.aecc.es/Paginas/PaginaPrincipal.aspx
http://www.airc.it/
http://www.aicr.org.uk/
http://www.ai.espaca.com/loginutenti.asp
http://www.arc-cancer.net/
http://www.aphp.fr/
http://www.ayudas.net/Septimo_Programa_Marco_Invesigacion_Desarrollo-11411BT1E2000R0P6O1PQ.html
http://www.bmbf.de/en/
http://www.cancer.dk/en+os/The+Danish+Cancer+Society.html
http://www.carreras-stiftung.de/
http://www.cnrs.fr/
http://www.curie.fr/en
http://www.de.kwfkankerbestrijding.nl/Pages/Home.aspx
http://www.dfg.de/index.jsp
http://www.en.dk/councils-commissions/the-danish-council-for-independent-research/scientific-research-councils/medical-sciences
http://www.fondazioneirc.it/
http://www.genomics.nl/
http://www.government.nl/ministries/vws
http://www.inserem.fr/
http://www.iscii.ies/
http://www.iss.it/chis/?lang=2
http://www.istruzione.it/web/hub/home
https://www.krebshilfe.de/
http://www.legatumori.it
http://www.ligue-cancer.net/
http://www.mineco.gob.es/portal/site/mineco/
http://www.obrasocial.lacaixa.es/
http://www.salute.gov.it/
http://www.wilhelm-sander-stiftung.de/cms/front_content.php
http://www.zonmw.nl/en/
Public funding

- Indirect investment in oncology research:
  - Health care systems
  - Universities

- Direct investment in oncology research:
  - Basic/translational research
  - Drug development (clinical research)

High number of financing organizations with small investment

- Higher investment in the UK, followed by Germany, France and Italy.
- Cancer research is considered a priority in the UK and the Netherlands, not in other EU countries (though increasing).
- Mainly through indirect sources (health care systems and Universities).

Direct investment:
- Mainly dedicated to basic research
- Clinical research focused on early phases
Distribution vs public investment:
- Similar to public investment in the UK.
- Higher than public investment in countries like Denmark and Sweden.
  - Almost non existence in countries like Spain or Ireland.

Many small organizations focused on specific cancer types

Some big organizations with a general focus and huge investment in cancer research (Trust42 in the UK)
Through big Pharma

Contribution trend to be underestimated (lack of information provided by industry):

- In 2004 3.1 B € in R&D in cancer worldwide.
- Estimated to be a quarter of the total cancer research investment.
Public-private collaboration

- Increasing worldwide and specifically in Europe.

![Pie charts showing internal and external R&D investment from 2003 to 2012.](chart)

- Big drug development centres in academic environments.
- Example of the NCRI in the UK

Spanish data: source BD metrics (14th edition)
The main objective is to promote independent academic research in the field of Oncology applied to a particular tumor type or several types of cancer, in order to translate this research into practical applicability to patients.

Other objectives include the dissemination of the obtained results and knowledge, contributing to the scientific evidence.

Contribution to continuous medical education.
Cooperative Groups: advantages

- Access to a broad, well-established network of highly qualified investigators and specialized hospitals and research centres.
- Input from internationally renowned opinion leaders in cancer research.
- Expertise in clinical trial design, conduct and analyses.
- Scientific credibility by having the study conducted independently.
- Money savings.
Cooperative Groups: different models

- According to area of research:
  - Multiple tumour types
  - Focused on one tumour type

- According to geography:
  - Local (one country)
  - International:
    - Direct membership of investigators
    - Network (group of groups)
ICORG is a non-profit association officially registered in Ireland in 1996.

ICORG is a collaboration of three parties – the Irish Clinical Oncology Research Group (ICORG) in Dublin, the Clinical Research Support Centre (CRSC) in Belfast, and oncology professionals throughout Northern Ireland and the Republic of Ireland.
Mission:
To enable Irish patients to gain early access to new cancer treatments.

Aims:
- To promote, design, conduct and facilitate clinical cancer research in the island of Ireland.
- Clinical cancer research means the investigation of methods of prevention, diagnosis, management and treatment of patients with cancer.
Affiliated members

20 Institutions
Local CG in breast cancer

GEICAM is a non-profit association officially registered in Spain on April 4th, 1995.

From June 2009 GEICAM is also a foundation registered in the Spanish Ministry of Education.
“Promote clinical, epidemiological and translational research as well as education and divulgation in Breast Cancer”
Affiliated members

Medical Oncologists (n=399)

- Pharmacologists fGEICAM (n=1)
- Radiologists/Nuclear Medicine dGEICAM (n=39)
- Pathologists/biologists pGEICAM (n=86)
- Radiation Oncologists/Physics rGEICAM (n=74)
- Surgeons/gynecologists qGEICAM (n=123)
- Epidemiologists/Prevention Medicine epiGEICAM (n=5)

Other: 3

Total: 730 members working in 181 institutions
Group structure

General Assembly (399 voting members)

Steering Committee (20+5+working groups coordinators + Scientific Director)

Renewal every three years

GEICAM Headquarter
The EORTC was founded as an international organization under Belgian law in 1962 by eminent oncologists working in the EU countries and Switzerland. It was named GECA and became the EORTC in 1968.

- 300 Universities or Hospitals
- 2500 Physicians
- 6000 new patients a year
- 30 countries
The aims of 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.
Affiliated members

European Union:
Belgium: 3
France: 7
Germany: 1
The Netherlands: 5
United Kingdom: 2
Italy: 1

Non-EU countries
Switzerland: 2

Last updated on 22 April 2013.
The primary interests of the EORTC are clinical trials that investigate strategic therapeutic questions that will influence medical practice or will fundamentally improve the understanding of a disease.

The EORTC Scientific Strategy encompasses the following types of clinical trials:

- Large phase III academic trials aimed to change the standard of care
- Trials with a strong translational research component
- Trials addressing rare tumor types
- Trials optimizing integration of new agents in therapeutic strategies.
### Groups

- Brain tumours
- Breast cancer
- Children’s Leukaemia
- Gastrointestinal tract cancer
- Genito-urinary cancers
- Gynaecological cancer
- Head and neck cancer
- Imaging
- Infectious diseases

- Leukaemia
- Lung cancer
- Melanoma
- Pathobiology
- Pharmacology and Molecular mechanisms group
- Quality of Life
- Radiation oncology
- Soft tissue and bone sarcoma

### Task forces

- Cancer in the elderly
- Cutaneous lymphoma
- Endocrine tumours
International network in breast cancer

Association founded by leading European opinion leaders in 1999. Network of 49 cooperative groups in 50 countries

- **31** EUROPE
- **1** CANADA
- **6** LATIN-AMERICA
- **2** AUSTRALIA
- **8** ASIA
BIG facilitates and accelerates breast cancer research at the international level by stimulating cooperation between its members and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry.
Group structure

General Assembly
(49 voting members)

Executive board:
9 members

Renewal every four years
Trials development and conduct

- **The “Lead” Model.** Trials led and run by the “BIG Network”. BIG HQ acting as coordinating data centre and providing statistical leadership (BrEAST Data Centre and Frontier Science Research and Technology Foundation). HERA and ALTTO.

- **The “Co-Lead” Model.** Trials led and run by a BIG Group, with one or more other partners, and in which the BIG HQ is involved as a “Co-Lead”. NeoOLYMPIA.

- **The “Supporter” Model.** Trials supported by the BIG umbrella, with a limited role for BIG HQ. PENELOPEB.
Thanks!