



International Collaboration in Cancer Research

Tanja Cufer

ASCO IAC, Immediate Past Chair

University Clinic Golnik, Medical Faculty Ljubljana, Slovenia

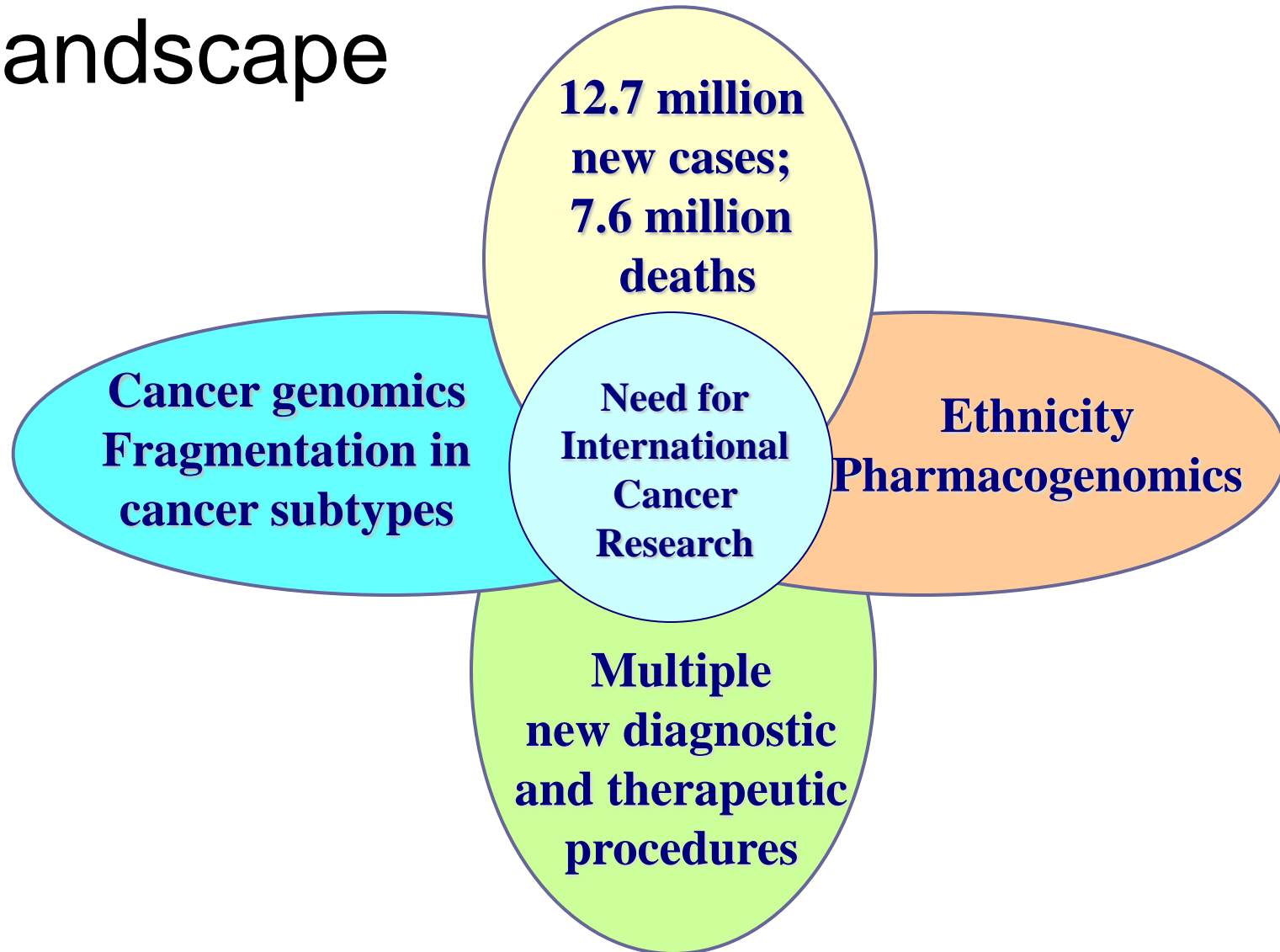
ESMO 2012



Disclosure

- I have no relevant commercial interest to disclose.

Cancer Clinical Trials : 21st Century Landscape





Need for 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
- To discourage national/small sized trials that are inconclusive, unethical and concomitantly conducted in several countries



International Clinical Cancer Research (CCR): 2012 Landscape

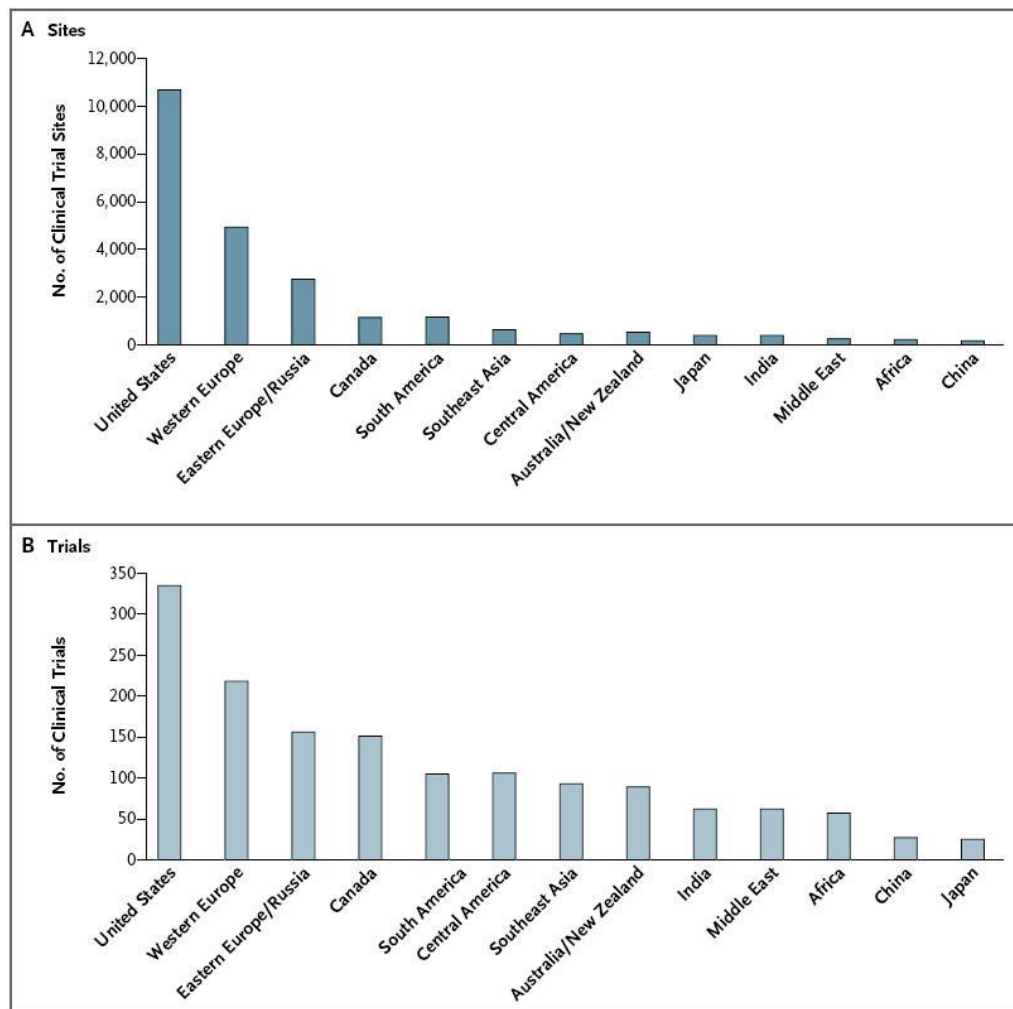
- Good news

- Slow but gradual increase of international CCR
- Higher level of ethical standards (GCP, Declaration of Helsinki)
- Higher transparency of CCR (web - based clinical trials platforms, ClinicalTrials.gov; etc.)

- Bad news

- Regulatory hurdles (lack of harmonization, increased costs and bureaucracy)
- Lack of independent funding
- Predominance of industry-driven international research

International Participation in Phase 3 Industry-Driven Clinical Trials

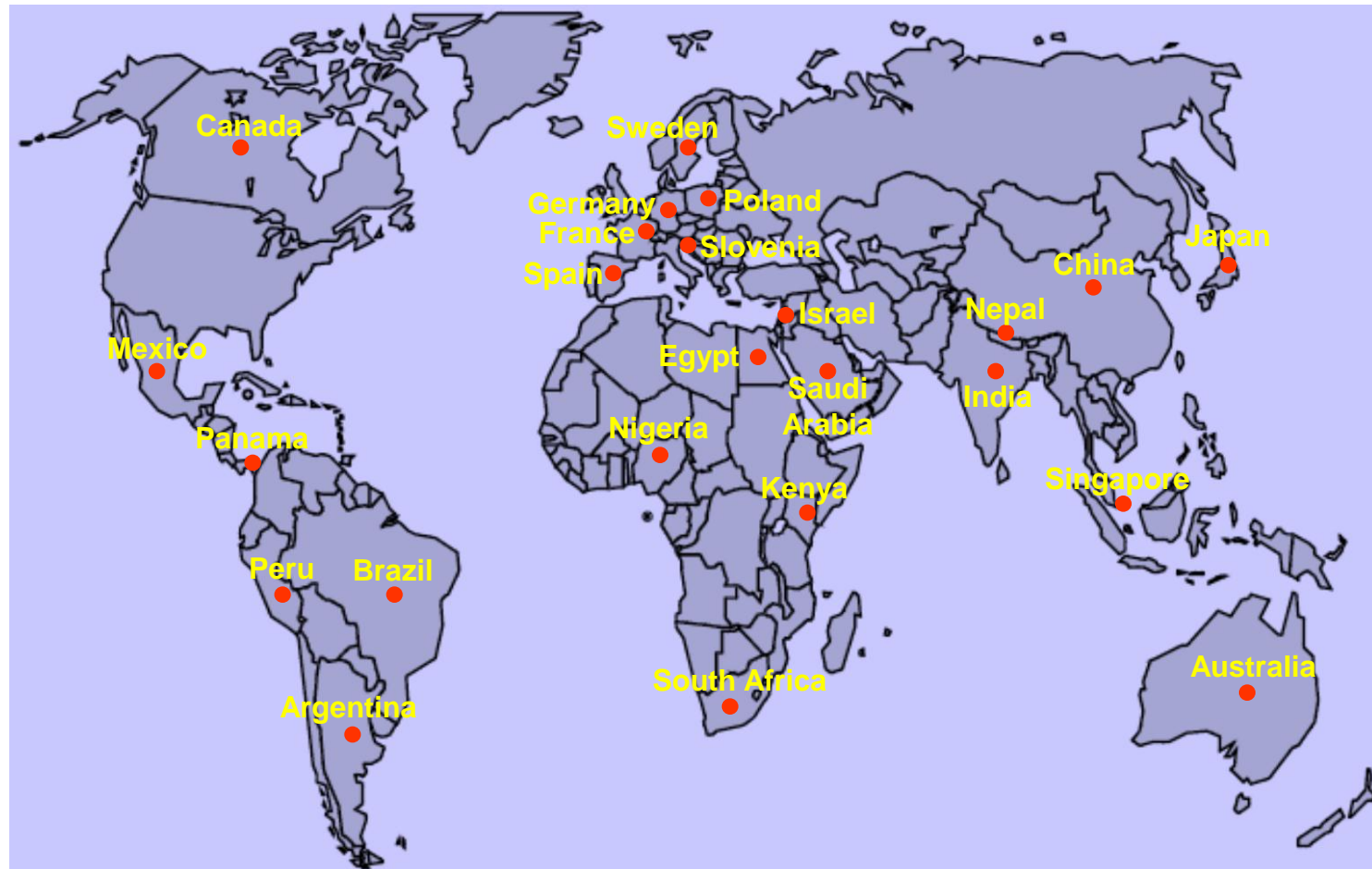




Harmonization of Technical and Ethical Standards

- ICH –GCP (International Conference on Harmonization Good Clinical Practice guidelines, 2001)
- Adverse event reporting (NCI CTCAE), tumor response assessment (RECIST criteria, 2000,2008)
- Declaration of Helsinki (adopted 1964, 2008, Ethics Committees, Informed Consent)
- Transparency of clinical research (Public trials registry, International committee of Medical Journals Editors, 2005)
- Guidelines and best practice for organization of the biobank core processes (OECD, NCI guidelines, TuBaFrost project)

ASCO IAC (International Affairs Committee) Survey on Challenges to Clinical Cancer Research



ASCO IAC Survey: Major Obstacles for ADCT

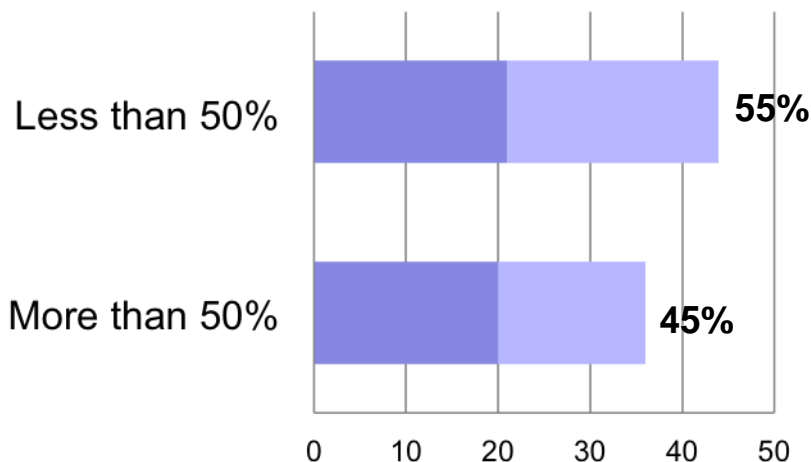
ranked from 1 (most) to 8 (least) important

	Average rank	HIC (n=41)	LMIC (n=39)
Competent authorities procedures	4.25	4.61	3.87
Ethics committee procedures	4.55	4.80	4.28
Insurance/indemnification coverage	4.55	4.54	4.56
Lack of patients/patient accrual	5.43	5.27	5.59
Lack of funding	3.16	3.15	3.18
Lack of research materials, e.g. drugs	4.49	4.49	4.49
Lack of trained personnel	5.00	4.90	5.10
Lack of time or competing priorities	4.58	4.24	4.92

funding vs. rest significant; patients vs. rest (except personnel) significant
marks change in obstacle distribution when stratified by country income

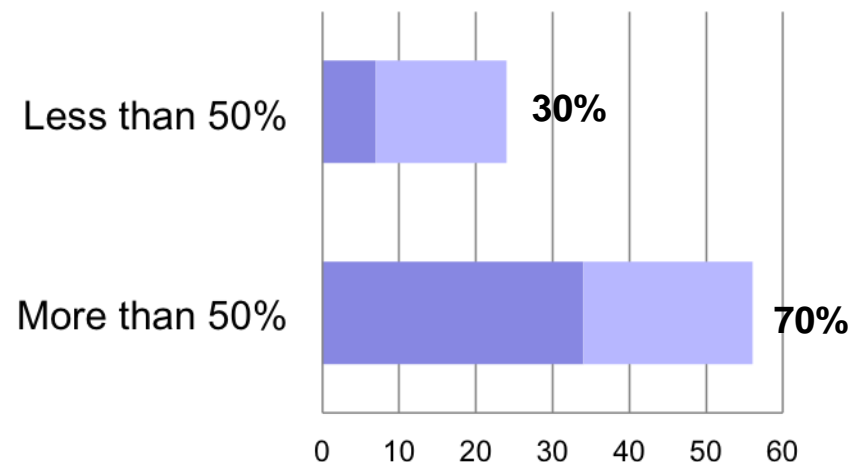
ASCO IAC Survey: Estimated percentage of ADCT/IDCT conducted with international collaboration

Academia-driven CT



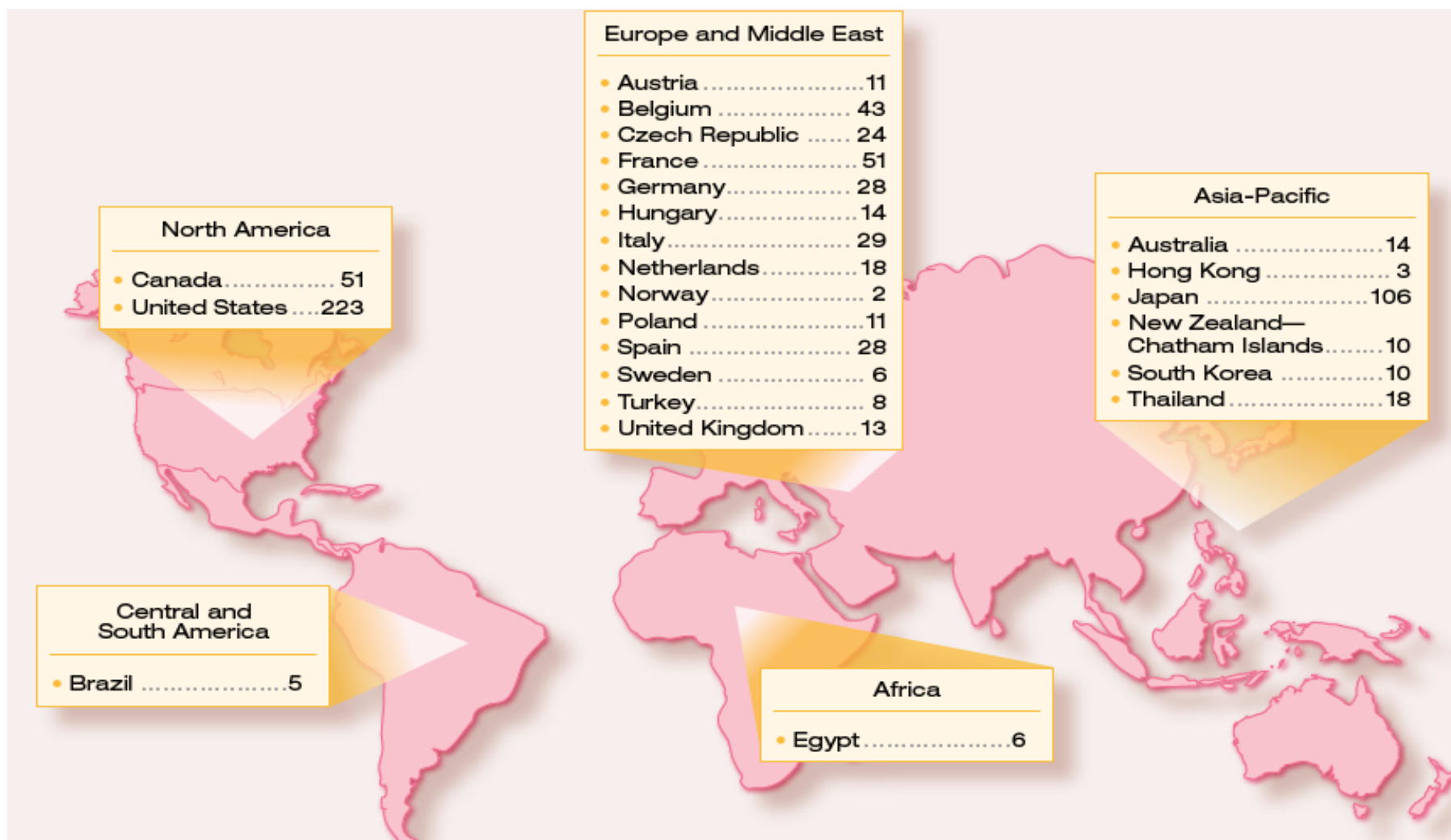
p=0.509

Industry-driven CT



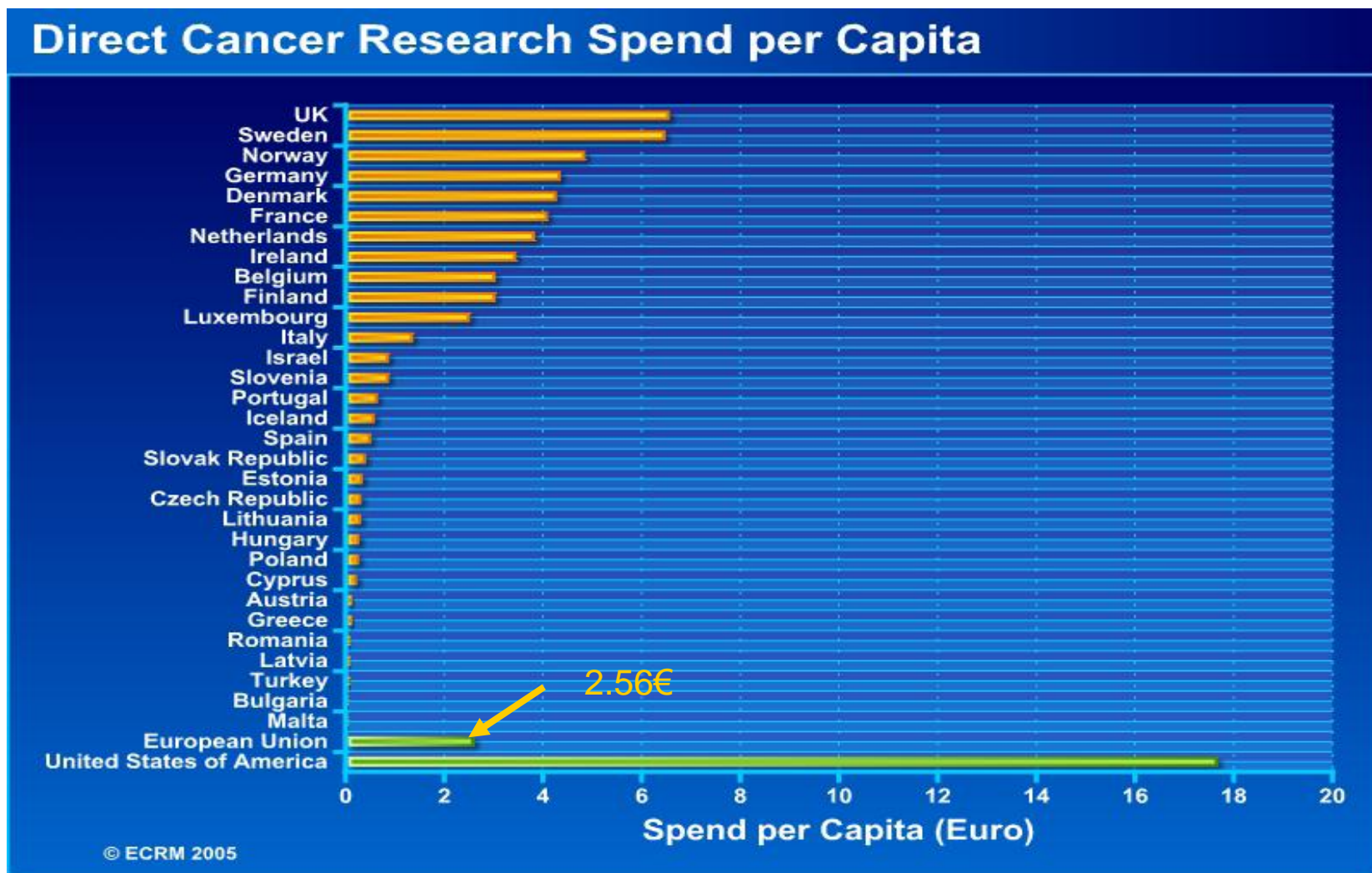
p=0.014

BOLERO-2: Everolimus in Postmenopausal HR-positive Advanced Breast Cancer

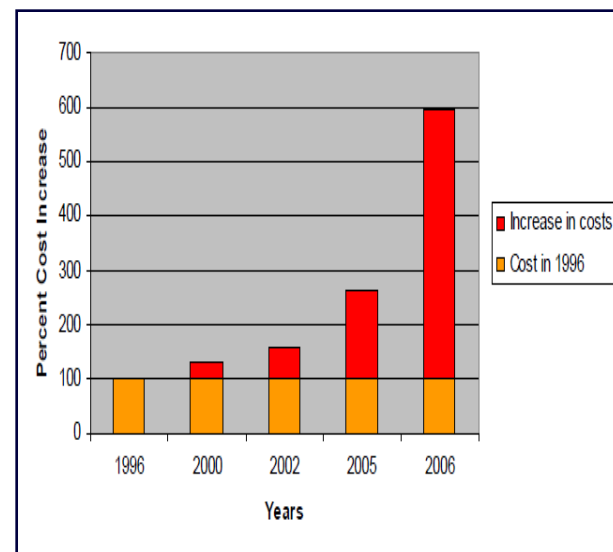
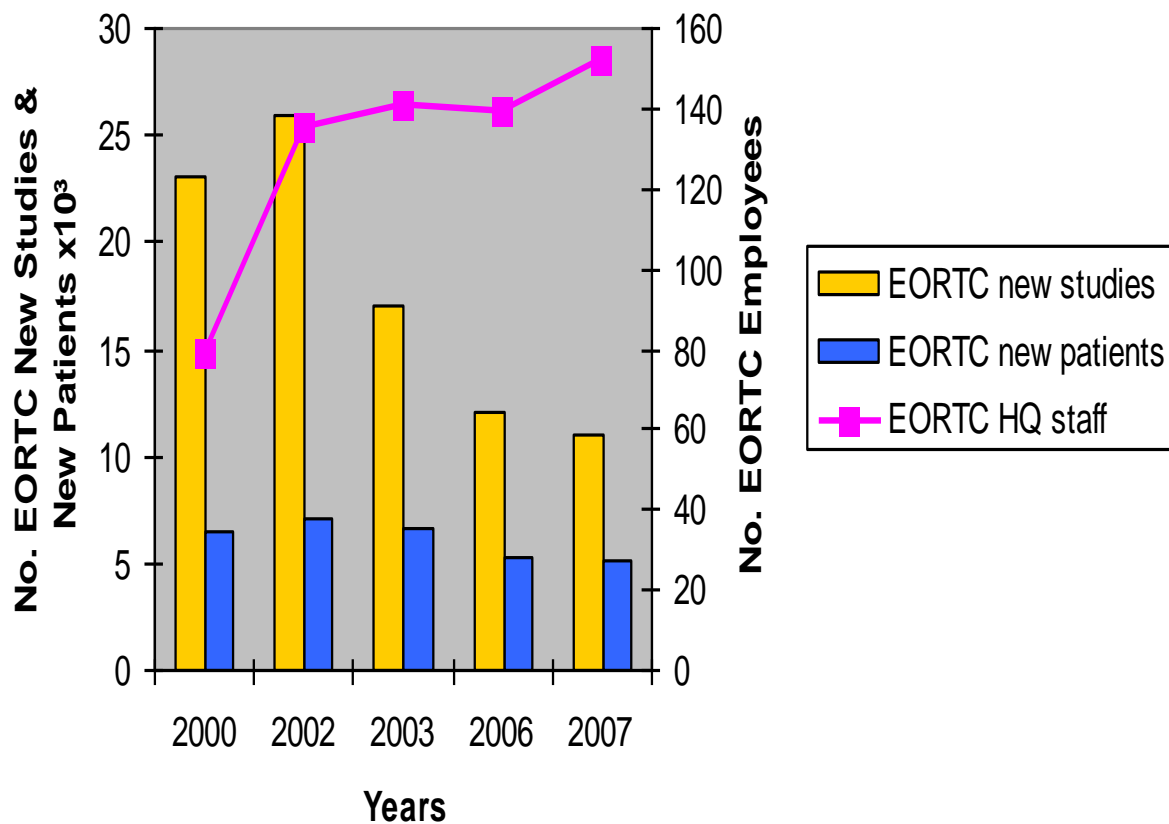


Lack of Independent Funding

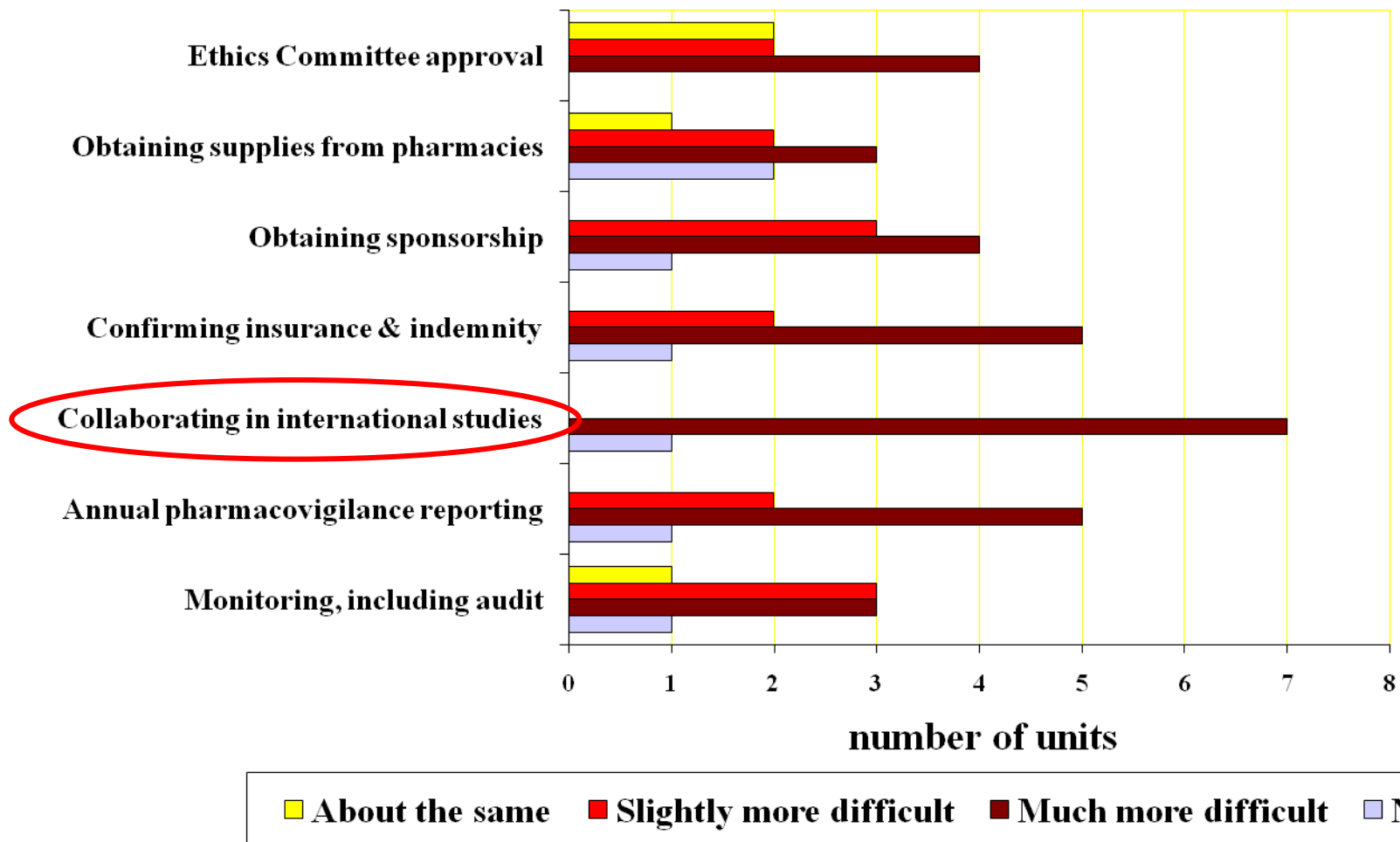
Spending on cancer research Per capita in 2002-2003



Regulatory Hurdles to Cancer Research - 2001/20/EC CTD

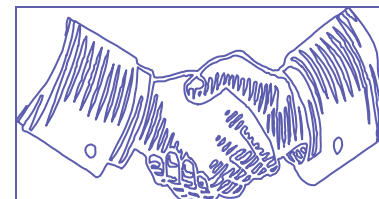
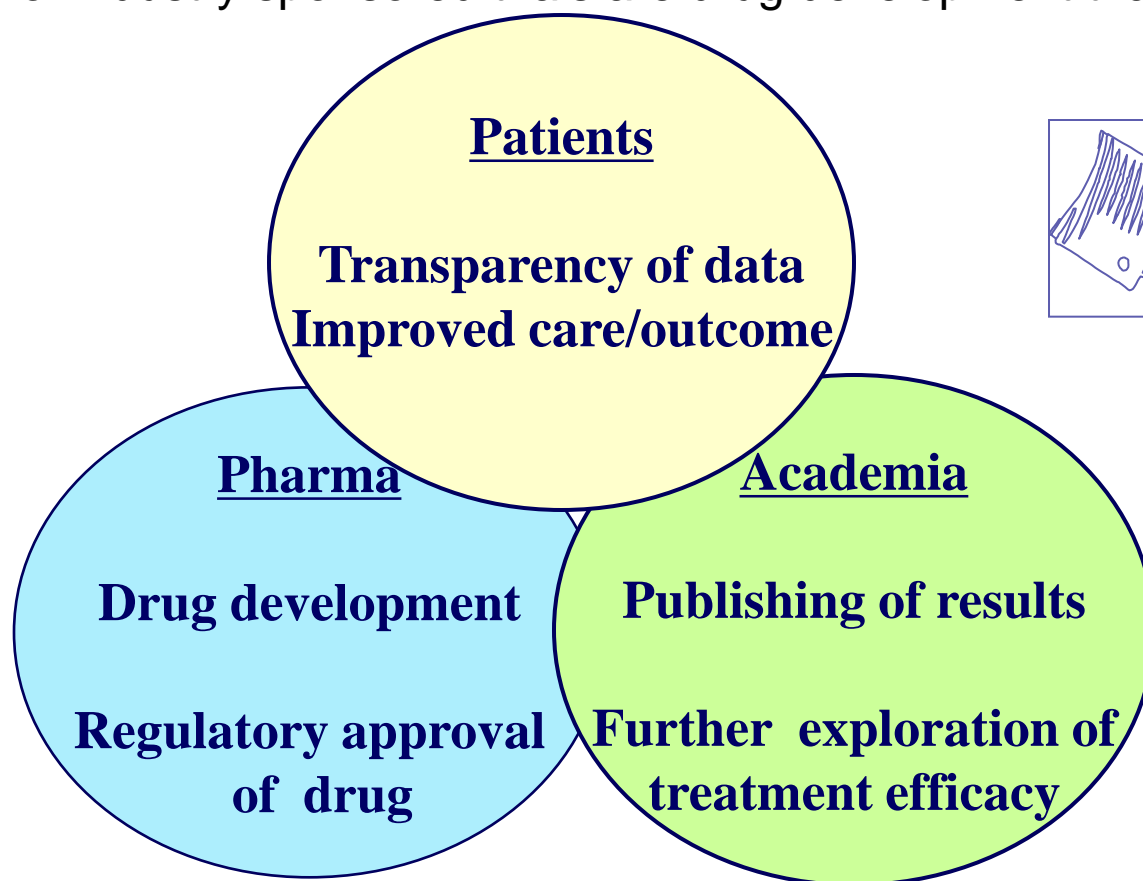


Impact of EU/CTD on Starting and Conducting Trials in UK



Strengthen International Research Through Partnership

- Industry is the prime sponsor of approx. 50% of clinical trials
- ... and approx. 70% of drug trials in oncology
- 93% of industry sponsored trials are drug development trials



nature



Keeping faith with trial volunteers

M. Piccart, A. Goldhirsch, W. Wood,
K. Pritchard, J. Baselga, L. Reaby,
I. Kössler, S. Kyriakides, L. Norton,
A. Coates

**Increased partnership between academia and industry
Win — win situation !**

- **Increased credibility of all clinical trials, increased participation of patients in clinical trials**

International Collaborative Groups



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

1988: Central and East European Oncology Group (CEEORG)

Scientific activity: 12 countries, 36 centres

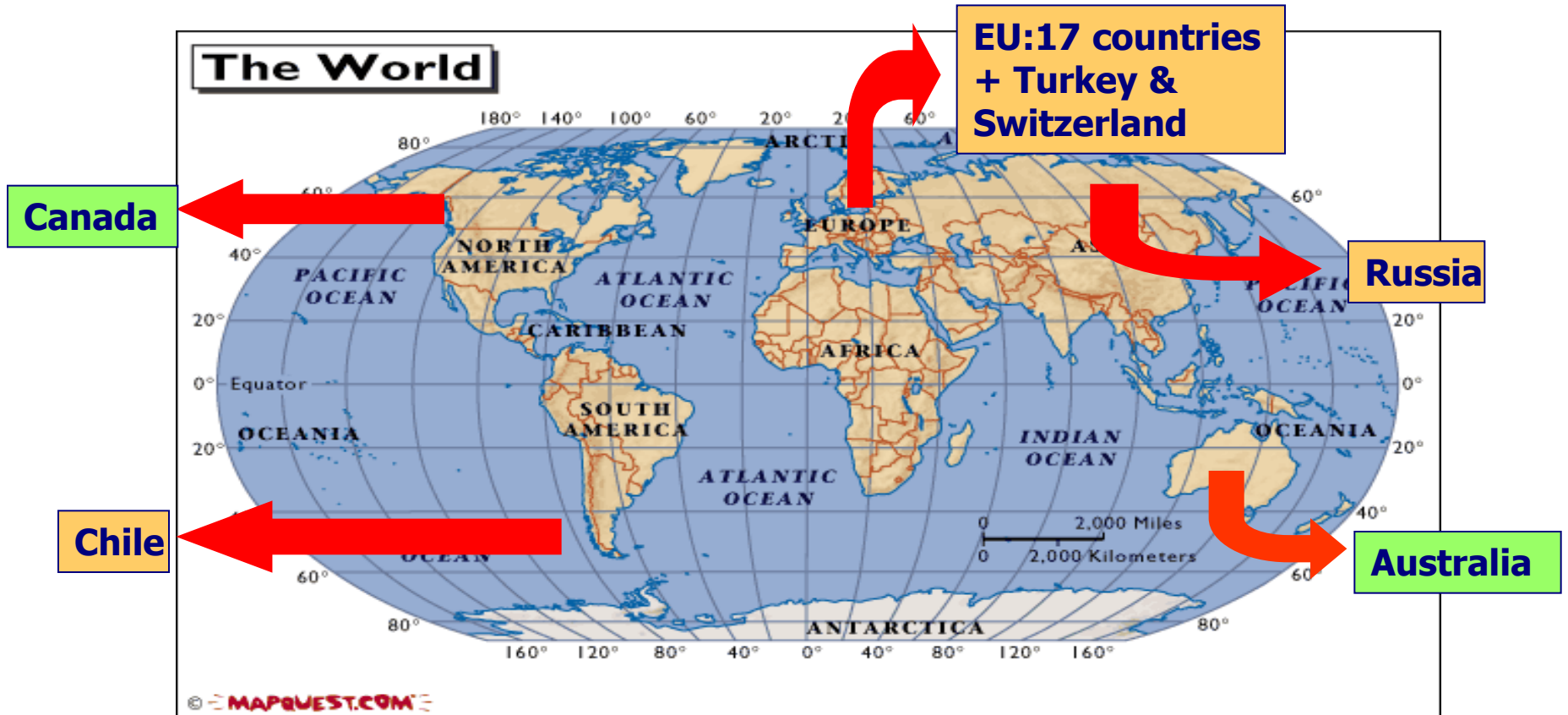




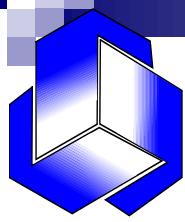
International Collaborative Groups

- EORTC (35 institutions, 11 European countries, Turkey, Egypt)
- NCIC-CTG
- International Network for Cancer Treatment and Research
- IAEA (International Atomic Energy Agency)
-

TRANSBIG: Partners



39 PARTNERS, 21 COUNTRIES



MINDACT:

Mi croarray for **N**ode Negative & 1 to 3 + LN **D**isease may **A**void **C**hemo **T**herapy

CLINICAL APPLICATION OF GENOMICS FOR IMPROVED TREATMENT TAILORING

BENEFITS:

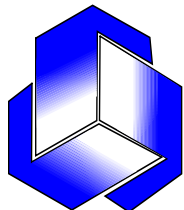
Only women who NEED chemotherapy RECEIVE it!

Reduce toxicity & side effects

Reduce cancer care costs

Reduce burden on health care systems





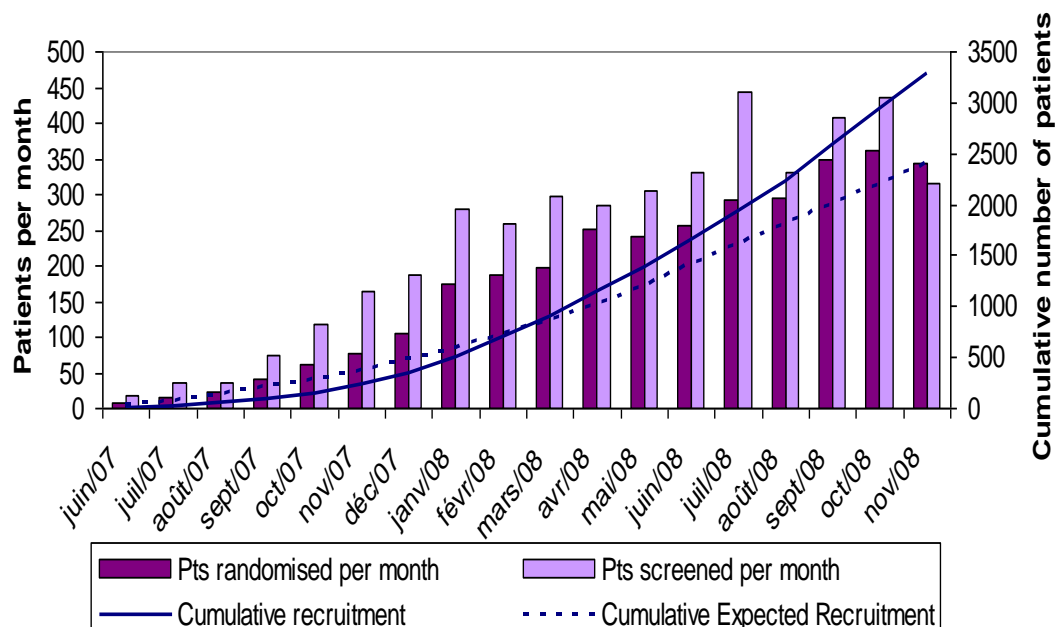
MINDACT trial: Example of a Successful Partnership



- Fast accrual
- Successful tissue collection
- Common SOPs on tissue handling
- Data collection, analysis and reporting in academia hands
- Tissue in academia hands
- Policy for access to data and/or sample
- Publication policies

ALTTO (Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation)

ALTTO Overall Recruitment Data



ACCOG	GBOC	NBCG
ANZ BCTG	GECO PERU	NCRI
AGO-NEO	GOCCHI	SBCG
BOOG	GOIRC	SOLTI
BrEAST	IBCSG/SAKK/EIO	TCOG
DBCG	ICCG	WSG
EORTC	ICORG	YBCRG
GBECAM	JBCRG	
GBG		

→ BIG

NCCTG / ECOG / SWOG / CALGB

→ TBCI

Improving International Collaboration

- Harmonization of regulatory issues
 - Fast review and approval of trials
 - Insurance requirements
 - Biobanking
- Increased independent funding
- Uniform criteria on academia and industry collaboration
 - Data collection, analyses and reporting (IDMC)
 - Tissue collection, storage and usage (TR SC)
- ***Set a common academic platform for clinical cancer research***
- ***Train the next generation of oncologists on independent clinical cancer research***



Slovensko predsedstvo EU 2008
Slovenian Presidency of the EU 2008
La Présidence slovène de l'UE 2008

European Conference THE BURDEN OF CANCER – HOW IT CAN BE REDUCED

Workshop IV CANCER RESEARCH – FINDING NEW SOLUTIONS IMPROVED COOPERATION

- Cancer research in Europe is still very fragmented and heterogeneous; more clinical/translational research needs to take place across Member State boundaries
- **Member states and EU commission should encourage closer collaboration between different research centres in Europe and pan-European cancer research through formation of the network of cancer research centres and through increased financial stimulation of pan-European projects.**

**The Burden
of Cancer – How Can it be Reduced?**

7 - 8 February 2008

1^{er} Curso Internacional de Investigación Clínica



Sede: **Asociación Médica Argentina** – Av. Santa Fe 117
Buenos Aires, Argentina. 20-21 de Abril de 2009.

ECCO - the European Cancer Organisation
American Association for Cancer Research (AACR)
American Society of Clinical Oncology (ASCO)

Jointly organise the ECCO-AACR-ASCO Workshop

METHODS IN CLINICAL CANCER RESEARCH

The 11th intensive workshop for European junior clinical oncologists in any clinical research specialty area, to learn the essentials of clinical trial

**20-26
JUNE
2009**

Park Hotel Waldhaus, Flims, Switzerland



International Clinical Trials Workshop

Cluj-Napoca
1st - 2nd of July 2011

OPERA PLAZA Hotel
Traian Mosoiu Street, no. 10-12
400132, Cluj-Napoca, RO

Faculty

Jan Bogaerts, statistician of the EORTC Breast Cancer Group, Brussels, Belgium

Fatima Cardoso, Head, Breast Cancer Unit, Champalimaud Cancer Center, Lisbon, Portugal

Eduardo Cazap, President of UICC and SLACOM, Buenos Aires, Argentina

Tudor Ciuleanu, MD, PhD, BUON national representative for ROMANIA, Cluj-Napoca, Romania

Tanja Cufer University Clinic Golnik, Slovenia, chairperson EORTC Breast Cancer Group, ASCO International Affairs Committee, Course Co-Chair

Alexandru Eniu, MD, PhD, Department of Breast Tumors, Cancer Institute Ion Chiricuta, Cluj-Napoca, Romania, Course Co-Chair

Meinolf Linn, Medical Director Oncology Central & South East Europe at GSK, Zurich, Switzerland

Ian F. Tannock MD, PhD, DSc, Professor of Medical Oncology, Princess Margaret Hospital and University of Toronto

Jo Anne Zujewski, Head - Breast Cancer Therapeutics (CTEP), National Cancer Institute, Bethesda, U.S.A.

*Thank you and cordially invited to ICTW, Opatija-
Croatia, June 12- 13th, 2013!*