COORDINATION AND ORGANISATION OF CLINICAL TRIALS

European Commission
Alliance for Biomedical Research in Europe
23 May 2012
Brussels

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EORTC Director General

EORTC *The future of cancer therapy*

Plan

- **The importance and challenges of international Clinical Trials**
- **Impact of the Clinical Trial Directive**
- **Revision of the Clinical Trial Directive**
- **Perspectives/Conclusions**

CLINICAL RESEARCH IS NOT A LUXURY BUT IS ESSENTIAL TO:

- Promote innovative research and rapid access to new agents
- Translate laboratory discoveries into practice
- Define state-of-the-art treatment
- Identify ineffective and/or redundant treatments
- Guarantee best medical practice for the benefit of patients

2 types of clinical trials:

- Independent evaluation of innovative agents (drug development).
- Test more effective therapeutic strategies (multi-disciplinary approach including surgery, radiotherapy etc…).

EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC)

Private and not for profit organization created in 1962

- Main mission:
  - promote and conduct research to improve cancer care
- Core activity: conduct clinical trials
  - International
  - Multidisciplinary
  - Develop new treatments
  - Define new standards of care
  - Large academic trials

Accrual of patients in EORTC studies (2000 – 2011) 71.905 patients

European Union:
Austria: 810
Belgium: 7.399
Bulgaria: 49
Cyprus: 73
Czech Republic: 160
Denmark: 529
Estonia: 7
Finland: 34
France: 14.438
Germany: 6.310
Greece: 48
Hungary: 210
Italy: 6.553
Latvia: 34
Luxemburg: 9
Malta: 20
Poland: 1.082
Portugal: 635
Republic of Ireland: 90
Romania: 20
Slovak Republic: 451

European Union (Con't):
Slovenia: 310
Spain: 2.867
Sweden: 595
The Netherlands: 15.279
United Kingdom: 6.620

Non-EU Countries
Bosnia: 8
Croatia: 352
Macedonia: 6
Norway: 454
Serbia : 261
Russia: 178
Switzerland: 1.438
Turkey: 631
Ukraine: 4

Rest of the World: 3.941 patients

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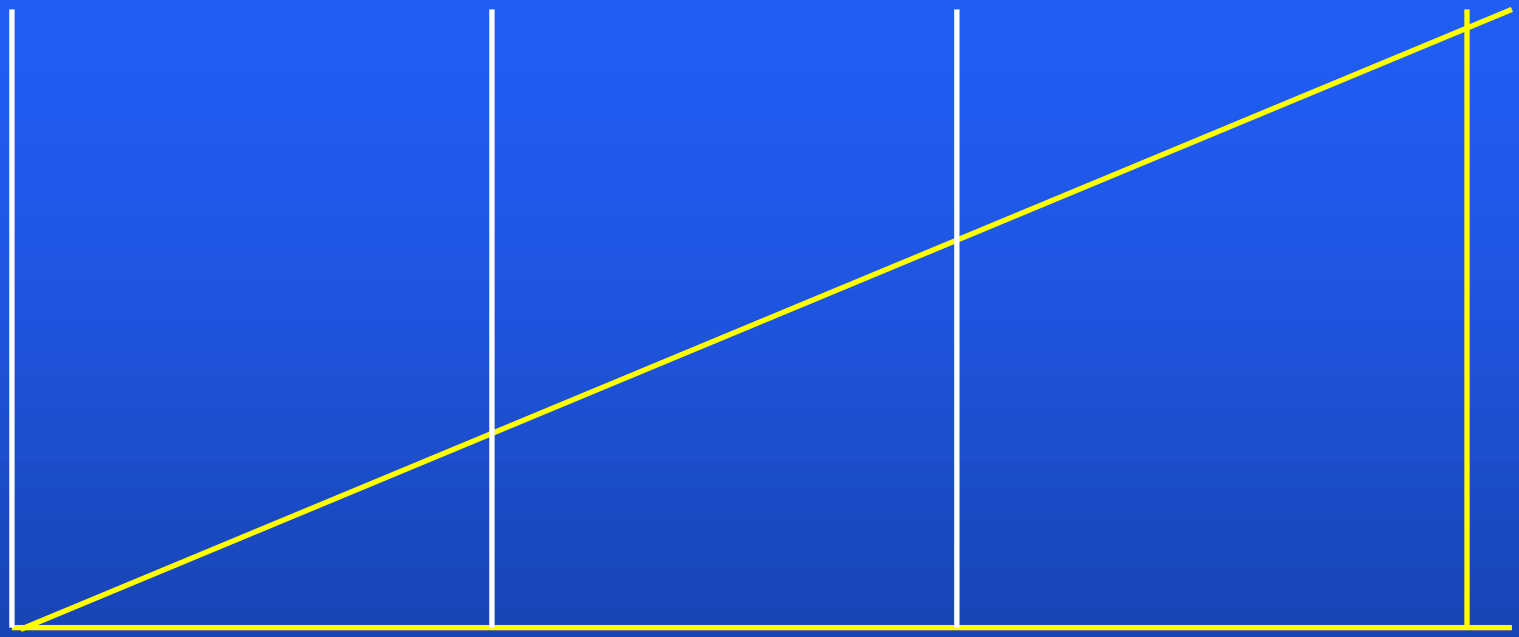
COMPLEXITY OF
Investigator Driven Clinical Trials



Single site investigator-driven

Multicenter single network national trials

Multicenter single network international trials

Multicenter multi-network trials international or transcontinental

Small exploratory trials

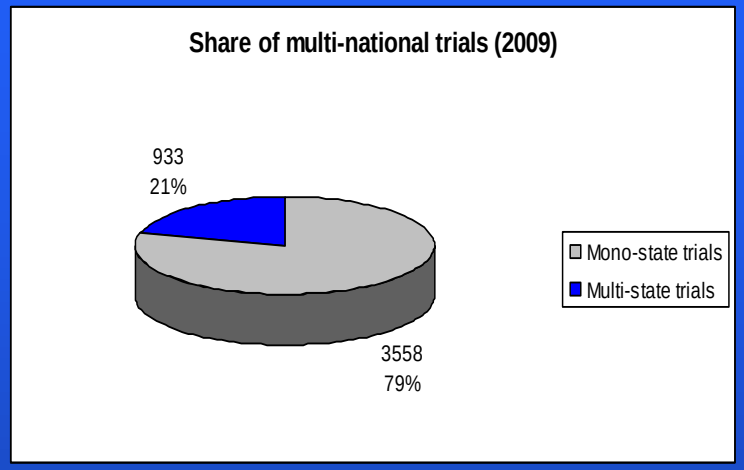
Large phase III with sub-studies and TR

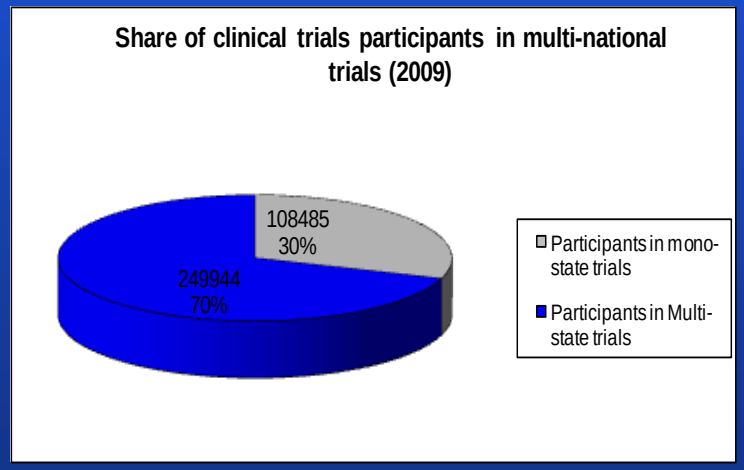
Necessity

August 22, 2011

?

Necessity and emergency





Stefan Führing, DG Sanco

Drop in number of EudraCT trials

2007 → 5028

2008 → 4627

2009 → 4619

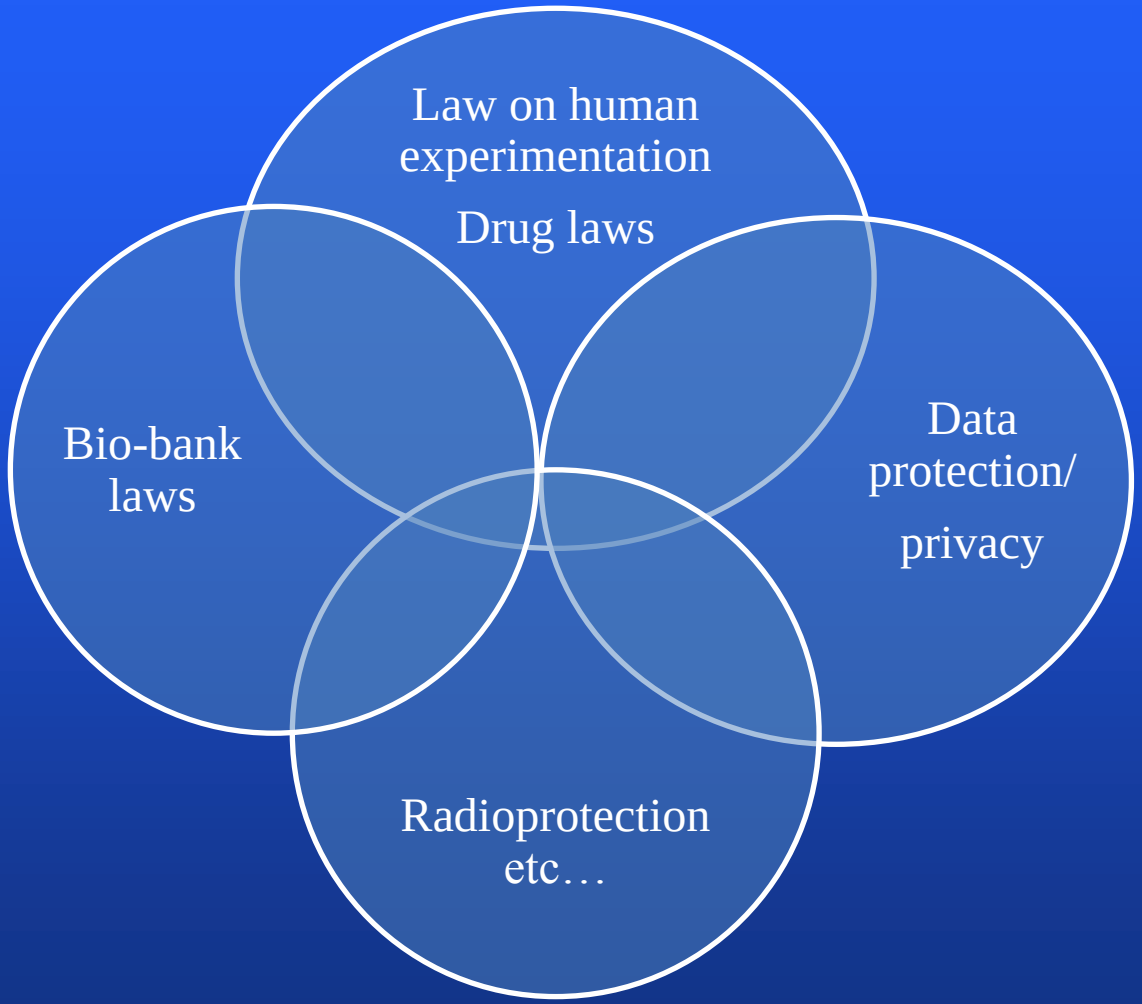
2010 → 4400

2011 → 3766

Fergus Sweeney, EMA

EORTC data:
From >20 new studies per year to < 10

Need to adapt to Complex and heterogeneous EU Legislations



Stop complaining and start acting

- **Late 90s- 1st version of the directive: few stakeholders were aware and/ or reacting.**
- **Since 2007: growing involvement of academics, industry, regulatory bodies and the patients.**
- **Numerous initiatives driven by EFGCP, EORTC, ECRIN, ESF-EMRC, ECPC, EPPOSI, EATG, EFPIA, FEAM and the European Commission.**
- **Constructive collaboration and growing consensus on concrete solutions: regulation.**
- **2012: Commission proposal to be submitted to the EU Parliament and later to the Council of the EU.**

REVISION OF THE EU CLINICAL TRIALS DIRECTIVE (1)

Streamline-Simplify-Harmonize

- Procedures for authorizing international clinical trials and submission of amendments:
  - Single electronic submission portal in English for CA & EC
  - Coordinated Assessment Procedure (CAP)

REVISION OF THE DIRECTIVE PROPOSALS (2)

- Real single EC opinion per country
- Safety reporting process simplification (SUSAR)
- Clarification of the roles of CAs and Ecs

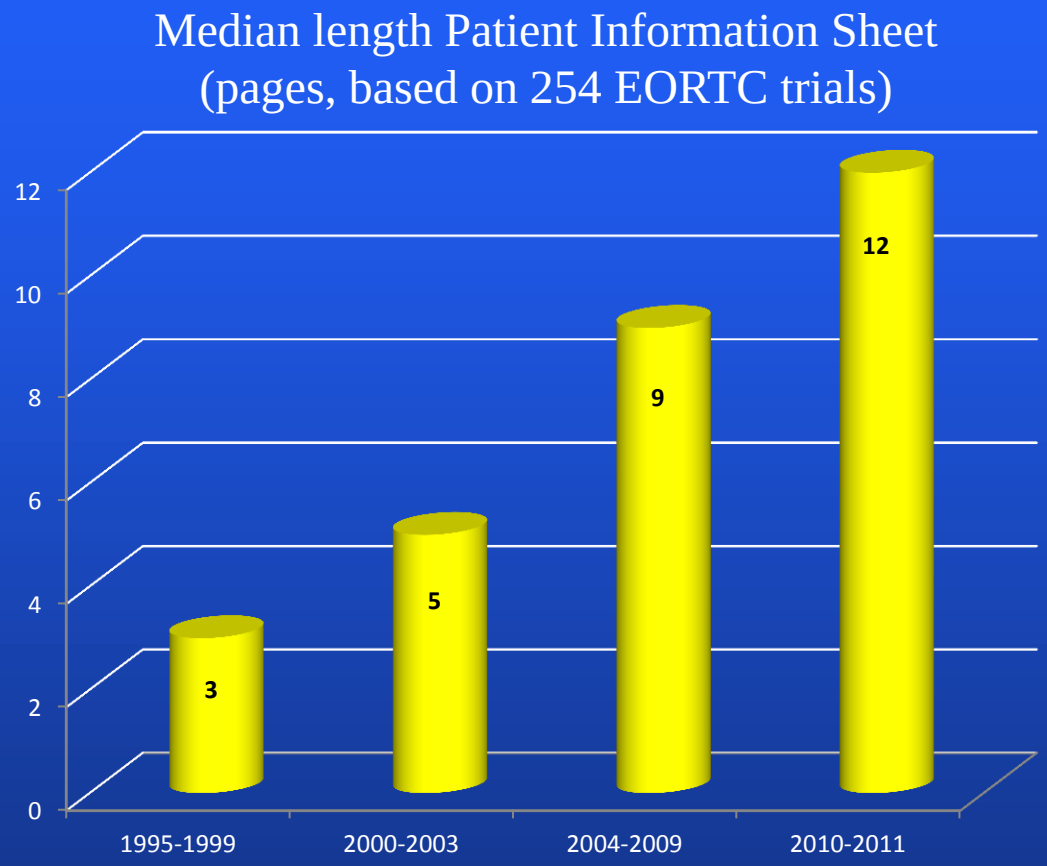
→ Positive feedback from new guidance on adverse event / reaction

- Risk based approach (assessed first by the sponsor and approved by Cap)
  - Regulatory
  - Pharmacovigilance
  - Monitoring
  - Insurance

REVISION OF THE DIRECTIVE PROPOSALS (3)

- IMP definition should exclude:
  - non-modified comparators available on the market
  - concomitant and background medications
  - Combination with:
    - surgery
    - radiotherapy

Does the legislation protect the researchers or the patients?



Uncertainty is inherent to scientific research

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Facing current reality

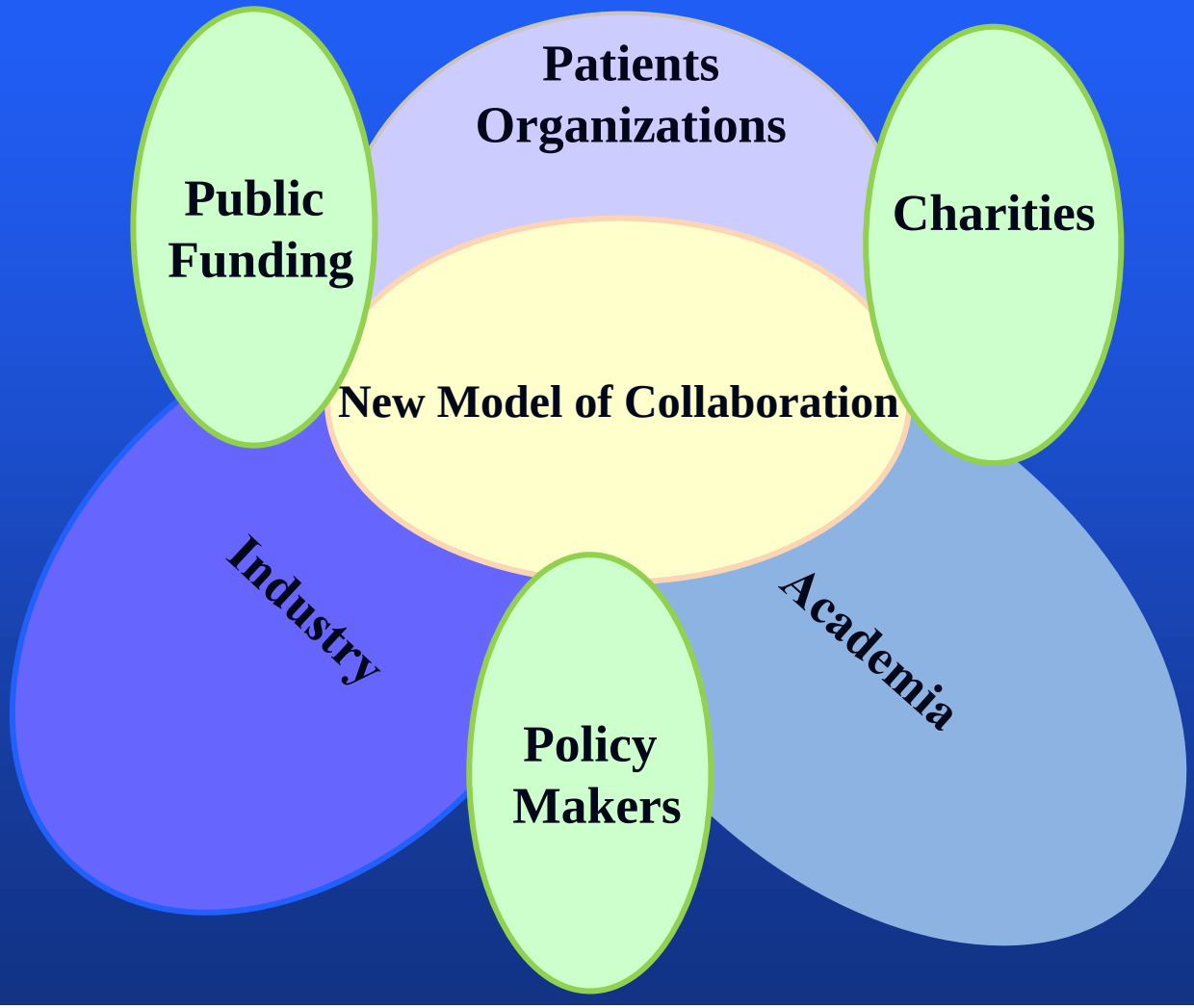
- Education and career tracks for clinical investigators (Young Generation) – Brain drain
- Less than 5% of patients participate in clinical trials
- Information to general public/politicians
- Building a bright future together requires:

Wisdom – Courage – Vision
and
Trust

ADDITIONAL CONCERNS

- Encourage stronger and new partnership with pharma while preserving academics independency (IMI)
- Funding pan-European Investigator Driven Clinical Trials:
- IPR/site contracts
- Appropriate infrastructures for:
  - local investigators
  - coordinating centers

CANCER CLINICAL TRIALS IN THE 21th CENTURY



THANK YOU FOR YOUR ATTENTION