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…).
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
Luxembourg: 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
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

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

Stefan Führing, DG Sanco
Need to adapt to Complex and heterogeneous EU Legislations

- Law on human experimentation
- Drug laws
- Bio-bank laws
- Data protection/privacy
- Radioprotection etc…
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.
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
• IMP definition should exclude:
  • non-modified comparators available on the market
  • concomitant and background medications
  • Combination with:
    o surgery
    o radiotherapy
Does the legislation protect the researchers or the patients?

Median length Patient Information Sheet (pages, based on 254 EORTC trials)

Uncertainty is inherent to scientific research
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 21st CENTURY

New Model of Collaboration

Public Funding

Patients Organizations

Charities

Industry

Academia

Policy Makers

EORTC The future of cancer therapy
THANK YOU FOR YOUR ATTENTION