Joining forces to promote evidence-based medical practice worldwide

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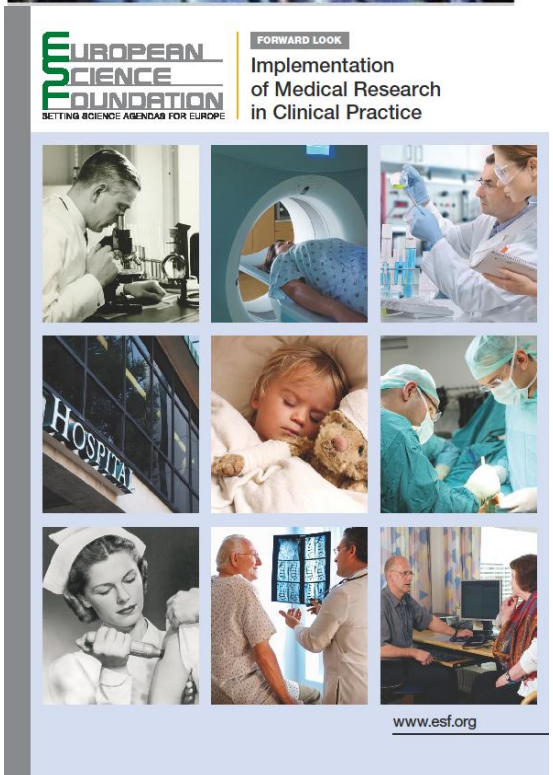
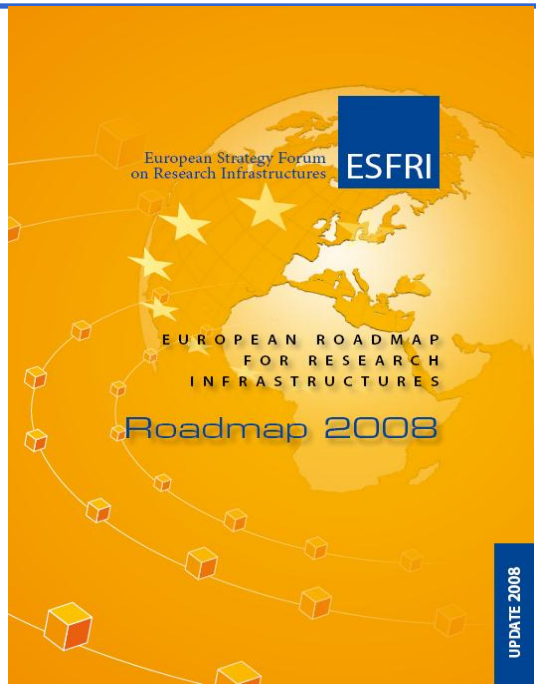
Promoting evidence-based decision in medical practice

- Clinical research
  - Development of innovative healthcare products and strategies
  - Comparative assessment of efficacy and safety of healthcare strategies
- Treatment optimisation and healthcare cost containment, for the benefit of health professionals, of health authorities and of patients worldwide
  - requires access to patients and expertise: global clinical research
  - requires knowledge transfer



1 - Need for infrastructure

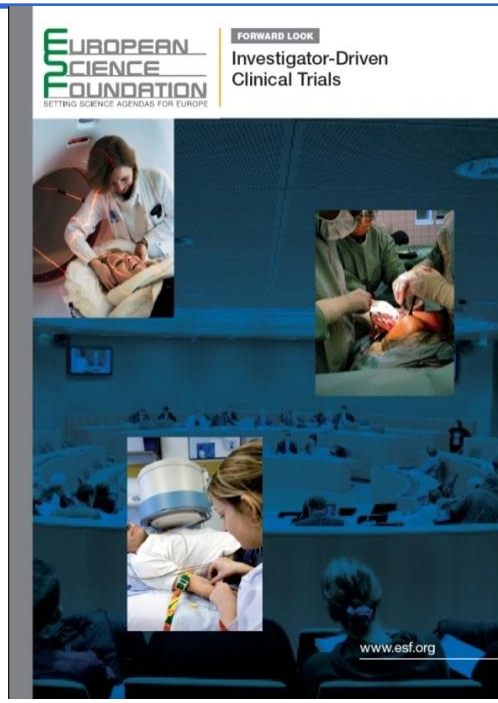
- Professional support to academic investigators and sponsors in
  - design, management, analysis of trial
  - patient investigation
  - able to support multinational trials
- Local, national and regional level
- Interoperable
  - Common standards, tools, practice
  - Harmonised training
- Globally connected
  - OECD GSF recommendation



2 - Need for harmonised and risk-adapted governance and legislation

- Revision of the 2001/20/EC clinical trials Directive
  - Regulation -> harmonisation
  - Simplification
  - Risk-based approach

- OECD Global Science Forum: facilitating multinational cooperation in non-commercial clinical trials
  - harmonisation
  - OECD Council Recommendation on risk-based governance
    - combined stratified and customised approach



3 - Need for funding to multinational clinical trials

- FP7 health priority
  "investigator-driven clinical trials"

- Comparative effectiveness research

- Innovative Medicines Initiative ?

- Combination of national funding sources ?

4 - Need for transparency and optimal use of data

- Why transparency in clinical research ?
  - Healthcare professionals and users of the healthcare systems deserve optimal use of efficacy and safety data, worldwide
  - Patients take personal risks to generate data
  - Tax payers contribute to the public funding
  - Journals and funding agencies need credible results and interpretation

1 - Registration of trial before recruitment

2 – Access to full protocol and amendments after completion

3 – Access to recruitment performance

4 - Disclosure of conflicts of interest, incentives

5 - Reporting of clinical trial results

6 - Access to raw, anonymised trial data after reporting

  - Re-analyses, meta-analyses
  - Quality of data, credibility of aggregated results and interpretation