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ECRIN

European Clinical Research Infrastructure Network

Impact on health and economy

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Clinical research: promoting evidence-based decision in medical practice

- ***what is the best treatment option for a disease condition / group of patients ?***
  - everybody knows: established guidelines
  - somebody knows: 'knowledge transfer'
  - nobody knows: clinical research
    - ✓ development of innovative health products
    - ✓ exploring new indications for existing drugs
    - ✓ comparative assessment of efficacy and safety of existing healthcare strategies

- ***treatment optimisation and healthcare cost containment, for the benefit of health professionals, of health authorities and of patients worldwide***

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK

European Strategy Forum
on Research Infrastructures

ESFRI

EUROPEAN ROADMAP FOR RESEARCH INFRASTRUCTURES

Report 2006

Make Europe a single area for clinical research

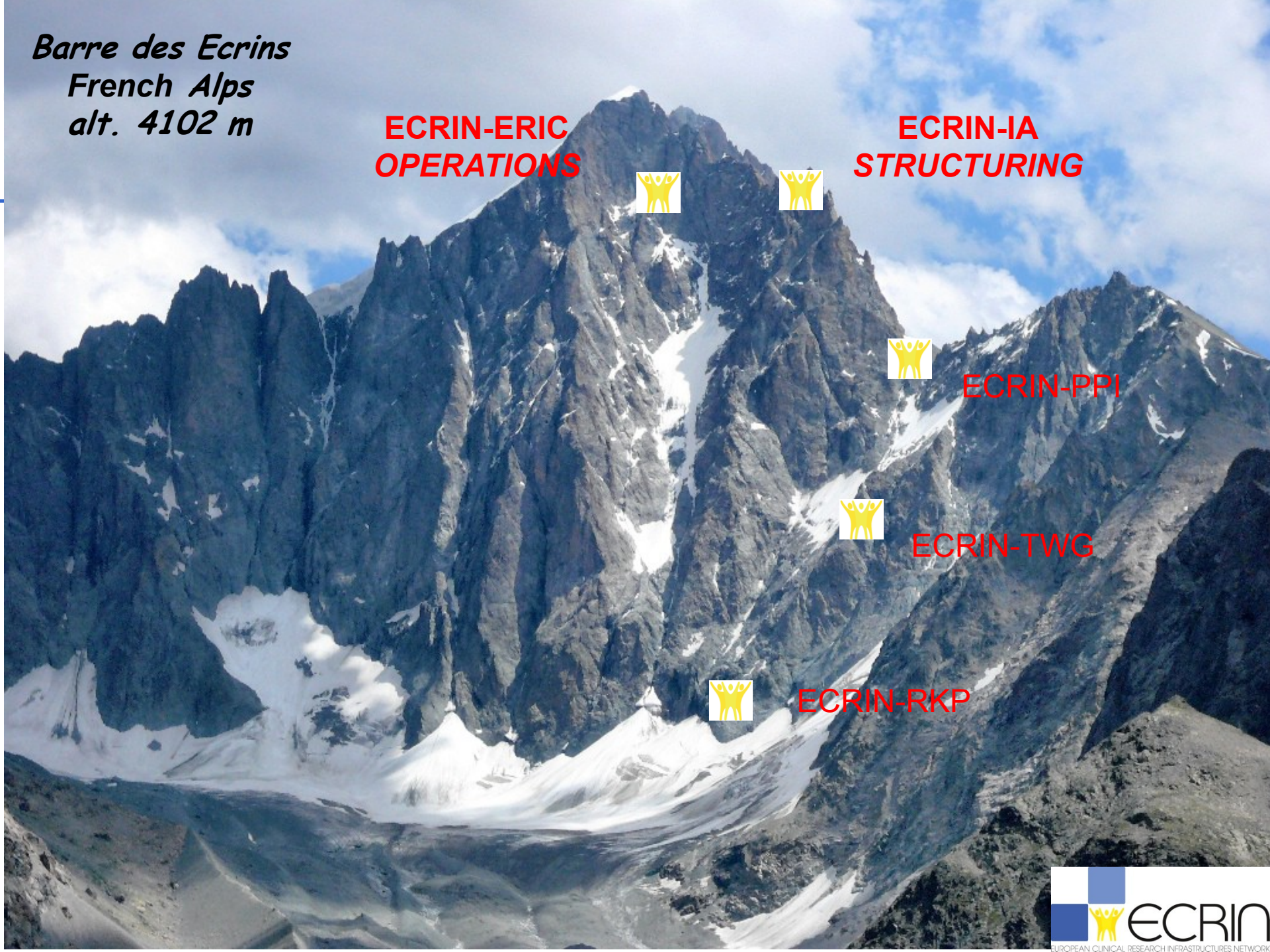
A pan-European infrastructure for clinical research in any disease area

Pan-European, distributed infrastructure providing coordinated services to ***multinational*** clinical research in Europe:

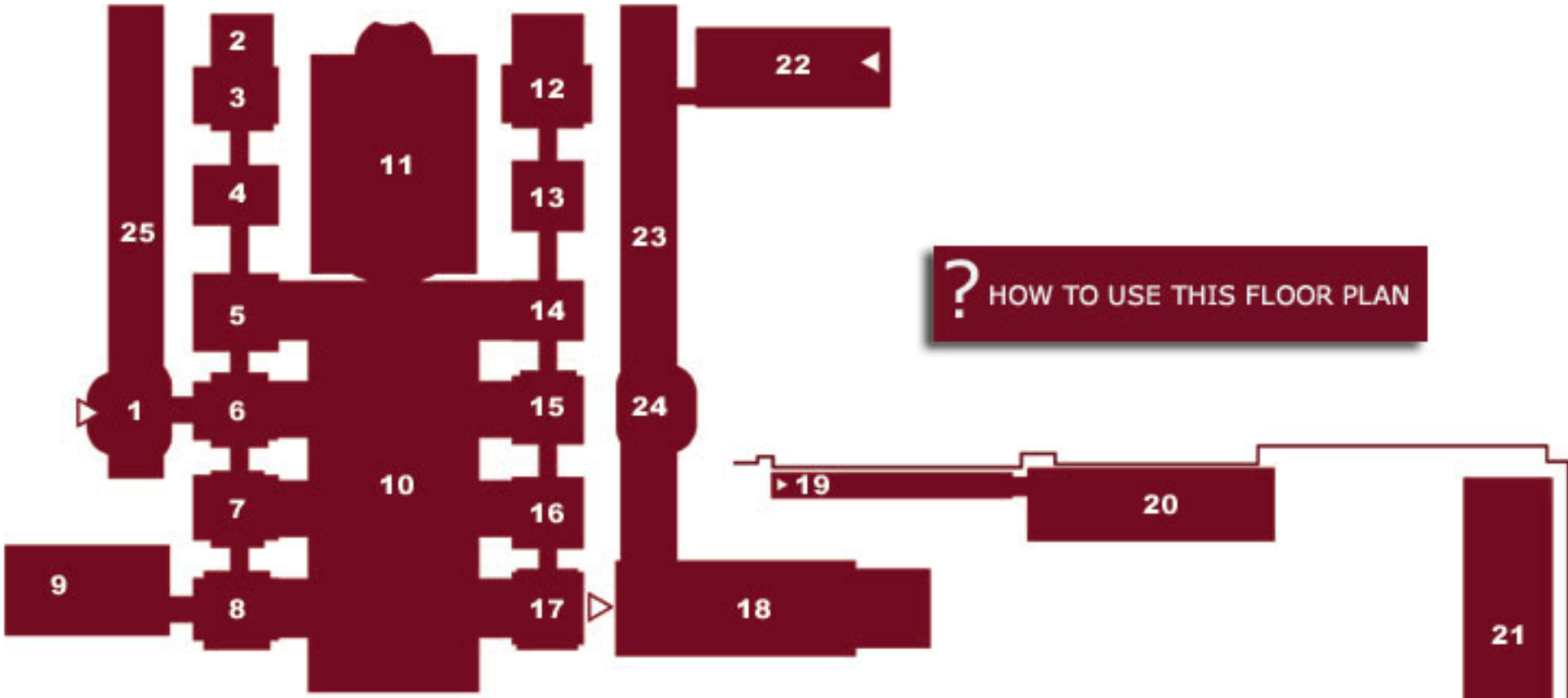
- access to ***patients*** and to ***expertise*** throughout Europe

- despite the ***fragmentation*** of health, legislative and funding systems

- ***support*** to investigators and sponsors in multinational studies


Barre des Ecrins
French Alps
alt. 4102 m
ECRIN-ERIC
OPERATIONS
ECRIN-IA
STRUCTURING
ECRIN-PPI
ECRIN-TWG
ECRIN-RKP
ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK

Model for a distributed infrastructure



List of Chapels

The chapel of the Langue of Castille, Leon and Portugal
The chapel of the Langue of Provence
The chapel of the Langue of Aragon
The chapel of the Langue of Auvergne
The chapel of Our Lady of Philermos
The chapel of the Langue of Italy
The chapel of the Langue of Germany
The chapel of the Langue of France
The chapel of the Anglo-Bavarian Langue

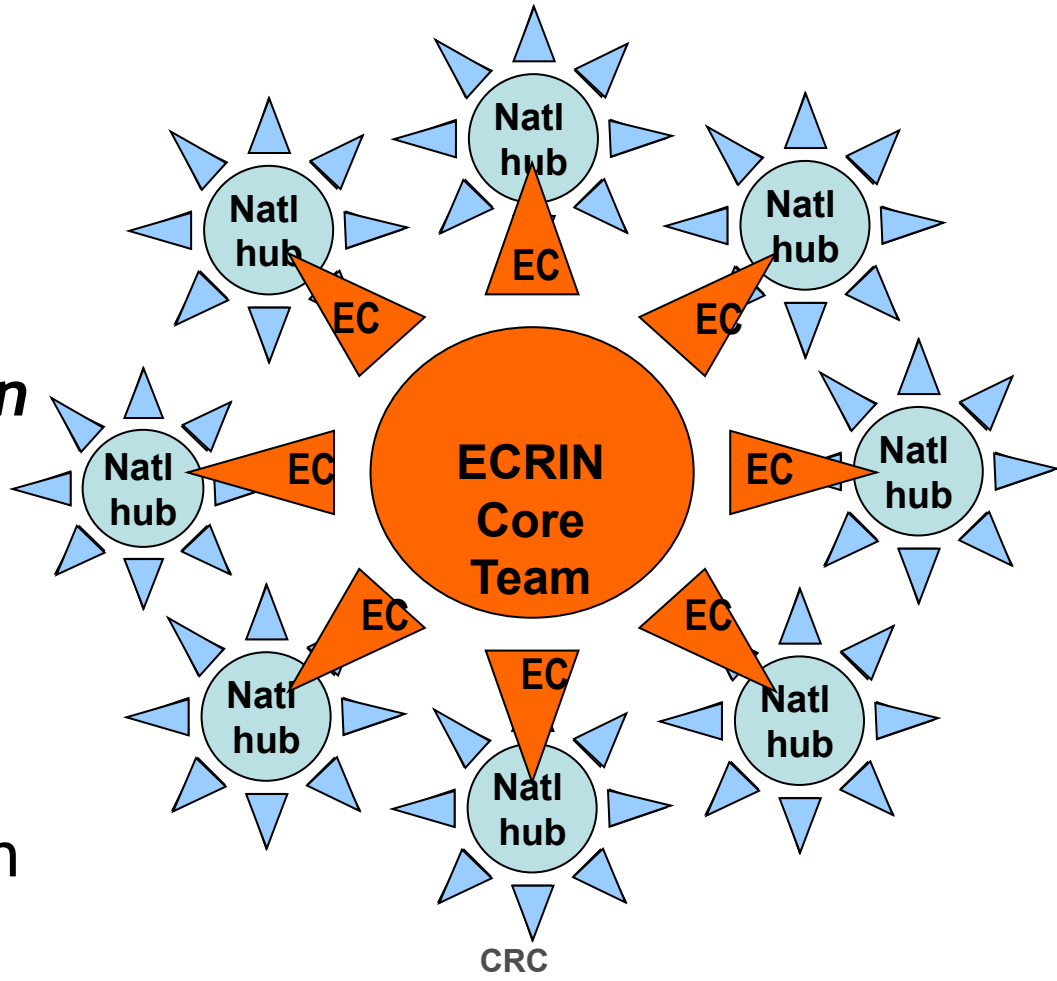
ECRIN-ERIC and scientific partners

- ECRIN ERIC
- Scientific Partners

(national networks & hubs)

Consortium agreements on

- Provision of services
- QA
- costs
- functional links between EuCo and hub



Investing in research and innovation

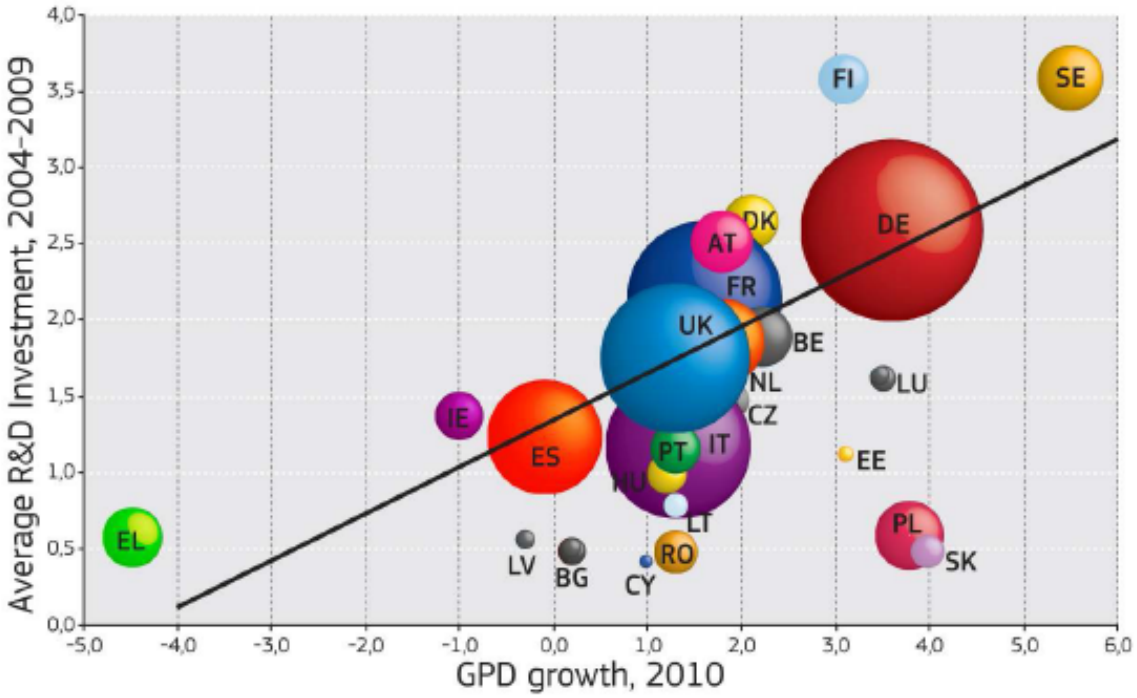
In which area ?

Priorities for citizens ?

Impact on citizens ?

Impact on economy ?

Investment in R&D is part of the solution to exit from the economic crises



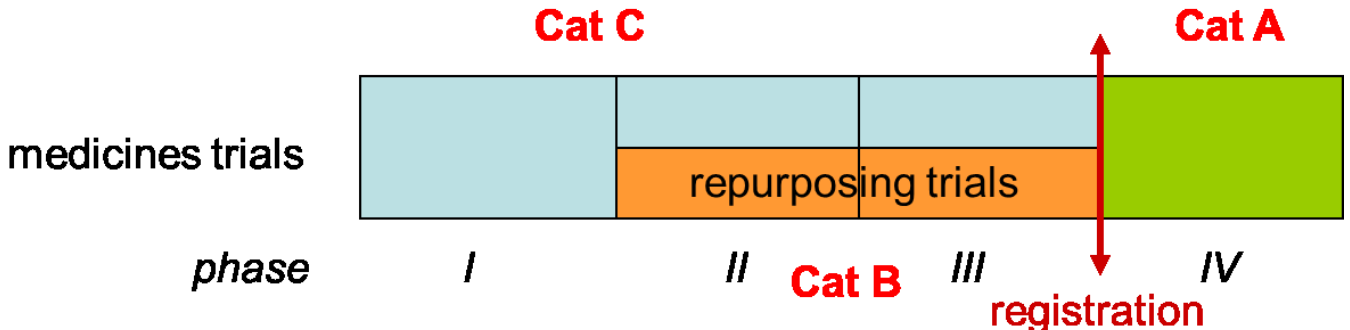
Research and Innovation

Health and economic impact of clinical trial infrastructure ?

- Critical issue in science and health policy, should drive political decision in funding clinical research infrastructure at the local, national, regional, global levels… but no data available

- As well as political decision in funding independent clinical trials:
  - Health priority "investigator-driven clinical trials"
  - Comparative effectiveness research
    - ➢ Which trials should be prioritized ?
    - ➢ Health authorities: pricing, reimbursement, evidence-based guidelines

- Infrastructures for non-commercial trials also enhance attractiveness for industry-drive



Health impact and return on investment of medical research ?

- Estimated 40% per annum
  - ad perpetuum
- For medical research as a whole,
  - not restricted to clinical research
- Public funding to
  - projects
  - infrastructures
- Combined impact on
  - Innovation
  - Healthcare cost containment
  - Improved healthcare strategies

  -> reduces burden of disease
    - Improved productivity of healthy population
    - Improved quality of life

Effect of a US National Institutes of Health programme of clinical trials on public health and costs

S Claiborne Johnston, John D Rootenberg, Shereen Katrak, Wade S Smith, Jacob S Elkins, ***Lancet*** **2006; 367: 1319–27**

- **Background**

Few attempts have been made to estimate the public return on investment in medical research. The total costs and benefits to society of a clinical trial, the final step in testing an intervention, can be estimated by evaluating the effect of trial results on medical care and health.

- **Methods**

All phase III randomised trials funded by the US National Institute of Neurological Disorders and Stroke before Jan 1, 2000, were included. Pertinent publications on use, cost to society, and health effects for each studied intervention were identified by systematic review, supplemented with data from other public and proprietary sources. Regardless of whether a trial was positive or negative, information on use of tested therapies was integrated with published per-use data on costs and health effect (converted to 2004 US$) to generate 10-year projections for the US population.

Effect of a US National Institutes of Health programme of clinical trials on public health and costs

S Claiborne Johnston, John D Rootenberg, Shereen Katrak, Wade S Smith, Jacob S Elkins, ***Lancet*** **2006; 367: 1319–27**

- **Findings**

28 trials with a total cost of $335 million were included. Six trials (21%) resulted in measurable improvements in health, and four (14%) resulted in cost savings to society. At 10 years, the programme of trials resulted in an estimated additional 470 000 quality-adjusted life years at a total cost of $3·6 billion (including costs of all trials and additional health-care and other expenditures). Valuing a quality-adjusted life year at per-head gross domestic product, the projected net benefit to society at 10-years was $15·2 billion. 95% CIs did not include a net loss at 10 years.

- **Implications**

For this institute, the public return on investment in clinical trials has been substantial. Although results led to increases in health-care expenditures, health gains were large and valuable

RoI = 5 times initial investment (trials plus healthcare expenditures) over 10 years.

Further steps: need for a structured research programme addressing:

- **Direct impact of clinical research infrastructures**
  - On innovation
  - On healthcare optimisation and evidence-based medicine
- **Indirect impact of clinical research infrastructures**
  - Capacity building
    - Also impacts attractiveness for industry trials
- **Impact of clinical research projects**
  - Innovation
    - Generates wealth (exporter countries)
    - Generates costs
  - Care optimisation, evidence-based medicine, cost containment
  - Productivity, quality of life