Third European Conference on
Research Infrastructures
Nottingham

From basic to clinical research

From research laboratories to Clinical infrastructures

Inserm

The French National Institute of Health and Medical Research

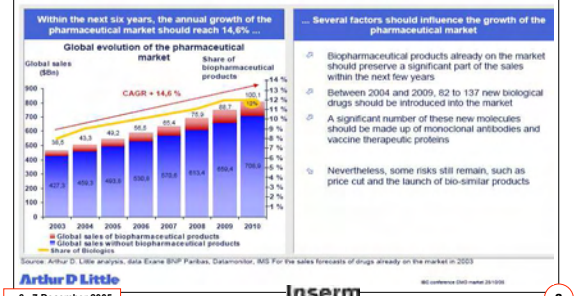
Christian Bréchot
Director General

Biomedical & Clinical Research : *the context*

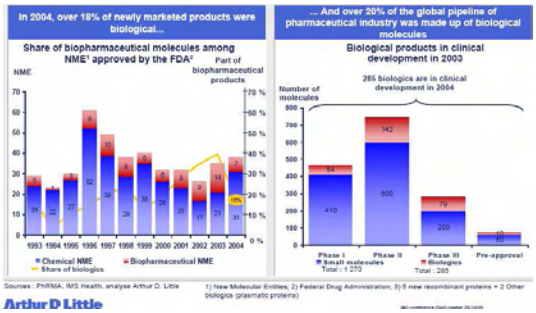
- High social & economical impacts : patients as end-users / Economic actors
- Drug discovery and development of new innovative therapeutic molecules
  - Faster
  - Cost-effectiveness
- Clinical benefit improvements
- Treatment of pathologies with strong unmet needs (Cancer, neurodegenerative diseases,…)

Biomedical & Clinical Research : *the challenge (4) of the Biopharmaceutical sector*

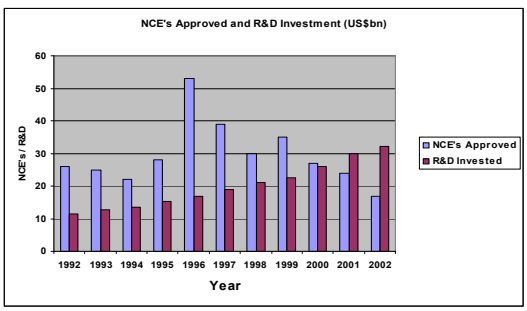
The biopharmaceutical market should reach over 100 billion dollars in 2010, and account for 12% of the global pharmaceutical market



Biomedical & Clinical Research : *the challenge of the Biopharmaceutical sector*



Biomedical & Clinical Research : *the challenge*



Biomedical & Clinical Research : *the challenge*

Between 1975-1994:
Europe ≈ US in terms of launch of **new molecular entities for human use** (NCE + NBE)

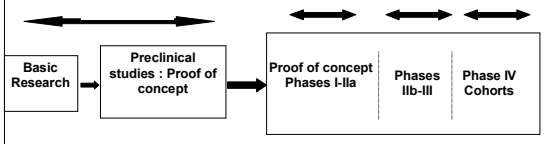
In 2002:

29 new molecular entities approved for human use worldwide:
8 from Europe, **13 from US**, **7 from Japan**
(1 from other countries)

The new "challenges" of the Clinical research in Europe

- To support development of new therapeutics molecules
  - Innovative **BASIC** research approaches
  - Innovative **CLINICAL research** : therapeutic and physio-pathologic studies
- To support Innovation and Biotechnology sector development
- To satisfy end-users (patients) requirements

Drug development, Clinical research & Infrastructures



Proposals to ESFRI

Steering Group on Research Infrastructures for *Biological and Medical Sciences*

First fields identified for analysis :

- Linking gene sequencing facilities, structural biology of macro-molecules and disease profiling
- Proteomics and protein production
- Proton therapy
- High security laboratories
- Clinical trials, related data banks and bio-process controls
- Imaging, neuroscience and mapping of the brain
- Systems biology, bio-informatics and enhanced computing capacity
- Biological banks
- Animal facilities and repositories

Inserm,

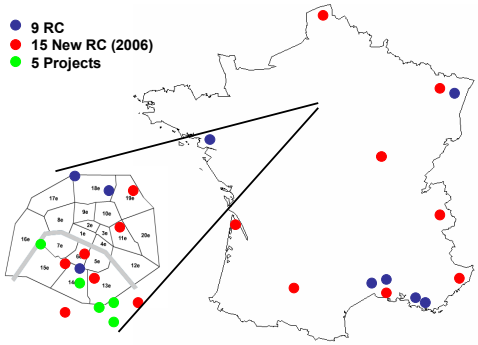
French National Institute of Health and Medical Research

- Created in 1964 from the National Institute of Hygiene and Hospital Research
- Working through the Ministries for Research and Health

The Inserm' priorities

- « *Researchers* »: new career tracks (European)
- Re-focus Inserm on its main mission: from basic to clinical research : translational research with a multidisciplinary approach
- Establish Inserm in a European and International context
- Develop public/private partnerships

Inserm – Research Centres - 2005



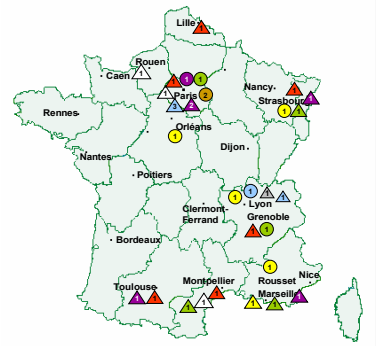
French Research Infrastructures Networks

- National Genomic Research Consortium: CNRG
  - National Sequencing Center
  - National Genotyping center
  - Regional Genopoles Core Facilities
- Biosafety-level 4 laboratory
- Local and regional technological infrastructures
- Clinical Research Infrastructures
- Cohorts, Biobanks and networks

10 National & 23 Regional infrastructures

National infrastructures : ○
Regional infrastructures : △

- Sequencing
- Transcriptomics
- Proteomics
- In vivo imaging
- Cellular imaging
- Electron microscopy
- Animal experiments Functional investigations
- Structural biology



Charter of research infrastructures (1)

Open access

- Platforms must be open to outside scientists whatever their affiliation (public or private)
- Personnel specially devoted to the platform respond to requests for services and assistance

Management

- A scientific committee including the person in charge of the platform and off-site users and experts define services offered and methodological updates, condition of access and fees, project priorities

Quality control

- The functioning of the platform requires quality control management based on the ISO 9001 norm - version 2000

Charter of life sciences infrastructures (2)

Technological update and valorization

- Platforms must support research of methodological nature generating publications or patents, licences, start-ups, …

Training

- Training of students, engineers and technicians

Evaluation

- Retrospective evaluations will be undertaken periodically by the group of experts and the results will determined subqsequent funding and specific staff allocations

ESFRI "list of opportunities"

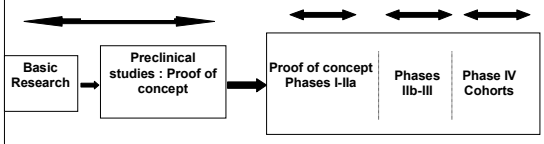
- Advanced infrastructures for brain and whole body imaging
- Bio-informatics infrastructures for Europe
- European network of advanced clinical research centres
- European network of bio-banks and genomic resources
- High security laboratories for emerging diseases and threats to public health
- Infrastructures for functional analysis of a whole mammalian genome
- Model testing facilities for biomedical research

High security BSL4 laboratory network

BSL4 laboratory network

- **Science Case:**
  - Diagnosis and Monitoring of special pathogens
  - Management of national banks of pathogenic agents
- **Technical case:**
  - Maintenance and security of the P4 lab.
  - Continuous training of people to work within this specific environment
  - Hosting of scientific teams on projects for specific pathogen
  - Collaboration and networking with other similar European P4 labs
- **Business Case:**
  - Construction costs : 70M€
  - Operating costs: 20M€/year

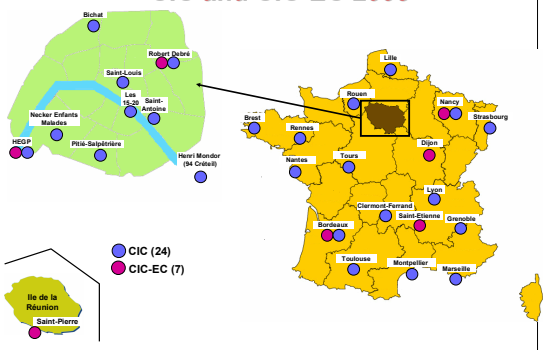
Drug development, Clinical research & Infrastructures



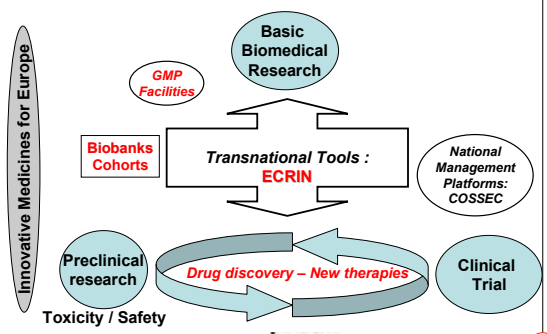
Clinical research infrastructures

		2001	2002	2003	2004	2005
Clinical research centers	24 7	17	21	28	31	36
Tissue banks	16 in 2001 14 in 2002 17 in 2003	16	30	47	47	47
Cohorts	65 Existantes 53 en cours	131	135	142	147	On progress
Registries	17 in 2001 12 in 2002 2 in 2004, 4 in 2005	17	29	29	31	35
Networks	9 regional in 2001 13 national in 2003	9	22	22	22	22

CIC and CIC-EC 2005



The Concept Case



Pan-European Clinical Research Centres Network

- **Science Case:**
  - Clinical research needs specialised competences and support of a set of services provided by infrastructures
  - Patients' investigation, databases, QA, monitoring, Regulatory, …
- **Technical case:**
  - Interconnection of national networks of academic clinical research infrastructures : Supranational infrastructures
  - Distributed competences centres
  - Coordination Team / European correspondents
  - Data management facilities / Biotherapy GMP and CRC facilities
- **Business Case:**
  - Construction costs : 35M€ (data centres, biotherapy GMP units,…)
  - Operating costs : 35M€ (Human resources and running costs)

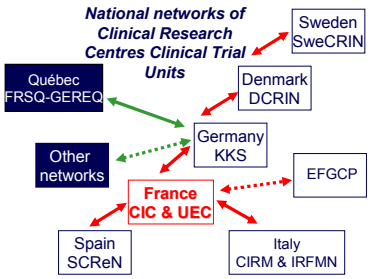
Pan-European Clinical Research Centres Network

and associated distributed GMP facilities

Pan-European network of Clinical research infrastructures: the *ECRIN* network of INSERM

ECRIN : European Clinical Research Infrastructures Network

ECRIN should be considered as a tool of the IMI that will allow:
- to access research facilities certified as compliant with the GMP/GLP standards in Europe
- to access expertise in the preparation and conduct of trans-national clinical trials
- to access scientific and ethic evaluations



ECRIN : a Platform of Integrated services to multinational studies

Integrated services (one-stop shop) to multinational studies

1 - interaction with ethics commitees
2 - interaction with competent authorities, regulatory affairs
3 - drug dispensing
4 - adverse event reporting
5 - data management
6 - study monitoring
7 - management of biological samples

GMP Facilities

- **Science Case:**
  - Reinforcing clinical research and translation of basic research to therapy
  - Production and evaluation of innovative therapeutic agents
- **Technical case:**
  - Production of new therapeutic/diagnostic agents from biotechnologies
  - Products for Cellular and Gene therapies
  - Good Manufacturing Practices (*GMO dissemination regulation*)
  - **Direct links with Clinical Research Centres (CRC - ECRIN)**
- **Business Case:**
  - Construction costs : 46M€ (new dedicated buildings and upgrading of existing ones)

Biobanks Biological Resources Centres

BRC

- **Science Case:**
  - A European network to coordinate European Scientific programs and policies
  - Innovative targets, Biomarkers, clinical studies
  - Technology transfer, dissemination of knowledge, valorisation
- **Technical case:**
  - Repositories for qualified biological samples (DNA, RNA, proteins,…), including clinical (physiopathology) data.
  - Providers/distributors of samples within scientific projects objectives
  - Development of QA standards for European BRCs
  - To keep samples for the future (inheritage)
- **Business Case:**
  - Construction costs : 12M€ (1M€/BRC)
  - Operating costs: 17M€ (running costs, information/dissemination,…)

Surgery and Imaging for Research & Education (CHIRE)

CHRU
Hôpitaux de Tours

The *CHIRE* project

- **Research**
  - Scientific competitiveness
  - Introduction of new methods of imaging (regional project called « *Centrimage* »)
- **Training**
  - Surgical skills (CHRU surgeons) & animal experimentations
  - Needs of dedicated equipments and facilities
- **Industrial relationships**
  - Development of products and new animal models through a research/industry partnership
  - Training of surgical teams to new skills and techniques