Clinical research: overview in France

Pr A. Syrota
President & CEO Inserm
President AVIESAN
Clinical research infrastructures: support to investigation and to study management

**Investigator-driven clinical research**
- Academic sponsors
  - Inserm, Direction de la Recherche Clinique et de l'Innovation, Groupement Inter-régional de la Recherche Clinique et de
- Data centres
- Support to study management
  - Clinical trial units (Unités de Recherche Clinique)

**Industry-sponsored clinical research**
- Industry sponsors
- SMEs
- Industry study management or CROs
- Interface with industry sponsors
  - CeNGEPS
  - Recruitment, contracting, networks

**Support to investigation**
- Early phase / experimental medicine: *Clinical Investigation Centres* (Clinical research facilities)
- Later phase: *Investigation networks*

Franco-British bilateral symposium
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  - Later phase: Investigation networks
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**Early phase / experimental medicine**
- Clinical Investigation Centres (Clinical research facilities)

Franco-British bilateral symposium
created in 1963, related to both Ministry of Research and Ministry of Health

The only French public organisation entirely dedicated to biological, medical and public health research

The largest European RPO devoted to biomedical research

Excellence and multidisciplinary research programmes on most human diseases, even the rarest ones

The link between the research laboratory and the hospital bed

Life and health sciences progress for better and affordable health care for patients
Franco-British bilateral symposium

INSERM PUBLICATIONS

Clinical Research

Basic Biomedical Research

+ 52% 126 pub/year 192 pub/year

+ 42% 95 pub/year 135 pub/year
A RESEARCH CONTINUUM

Franco-British bilateral symposium
Sponsor: Inserm

- Coverage: National
- Type: Oriented towards clinical translational research (clinical studies in relation with results obtained in Inserm units)
- Missions
  - Regulatory aspects
  - Pharmacovigilance
  - +/- monitoring
  - Budget and contracts (Inserm Transfert)
- About 150 studies (40 new projects each year)
- Limited funding to support clinical projects
- Special department for AIDS and viral hepatitis (Agence Nationale de Recherche sur le SIDA)
Inserm sponsor : protocols

- Molecular and structural bases of living organisms
- Cell biology, development and evolution
- Cancer
- Circulation, metabolism, nutrition
- Genetics, genomics and bioinformatics
- Immunology, hematology, pneumology
- Microbiology and infectious diseases
- Neurosciences, cognitive sciences, neurology and psychiatry
- Public Health
- Health technologies

Medical devices: 3%
Cell and gene therapy: 1%
Therapeutical trial: 12%
Pathophysiology: 80%

Total: 100%
Academic sponsors

41 Directions de la Recherche Clinique et de l'Innovation

- **Coverage**: Local > national
  - Located in hospitals
  - Mostly University hospitals (28)
- **Type**: projects with direct impact on patients care and health
- **Missions**
  - Regulatory aspects
  - Pharmacovigilance
  - Monitoring
  - Budget and contracts
- **Limited funding to support clinical projects**
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Later phase: *Investigation networks*

Support to investigation

Early phase / experimental medicine: *Clinical Investigation Centres (Clinical research facilities)*
Study management
Unités de Recherche Clinique

• University Hospitals:
  – Methodology and biostatistics

• Inserm
  – Inserm units
    • Methodology and biostatistics
    • +/- data centres
  – Service Commun 10: Infectious diseases
    • Methodology
    • Data centre
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**Data centres**

**Support to study management**

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**Later phase: Investigation networks**

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**Early phase / experimental medicine: Clinical Investigation Centres**

*(Clinical research facilities)*
Clinical Investigation Centres

• Joint programme: Inserm and Ministry of Health
• Located in a University hospital
• Both a platform and a Clinical research Unit
  – To provide investigators with clinical research facilities in a working environment that complies with European clinical and ethical directives
    ➢ Design
    ➢ Management
    ➢ Analysis
  - For academic and industry-sponsored studies
  - Investigators and personnel training
• Scientific evaluation (similar to the Inserm research units)
• Quality audits
Clinical Investigation Centres

1992
27 CIC General

2004
9 CIC Epidemiology

2005
10 CIC Biotherapies

2007
8 CIC Medical Devices
Map of the 41 Clinical Investigation Centres

Type of CICs
- CIC-P (27)
- CIC-EC (9)
- CIC-BT (10)
- CIC-IT (8)
- 11 multi-module CIC
Types of protocols

- Proof of concept (Phase I-II): 29%
- Phase III: 25%
- Phase IV: 4%
- Epidemiology: 17%
- Pathophysiology: 25%
### Bibliometry

<table>
<thead>
<tr>
<th>Year</th>
<th>Publications</th>
<th>IF &gt; 5</th>
<th>Top 1 %</th>
<th>Top 10 %</th>
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<td>2005-08/2011</td>
<td>4033</td>
<td>1338 (33 %)</td>
<td>198 (4.9 %)</td>
<td>719 (17.8 %)</td>
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<tr>
<td>2009</td>
<td>750</td>
<td>222</td>
<td>35 (4.7 %)</td>
<td>128 (17.1 %)</td>
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<tr>
<td>2010</td>
<td>958</td>
<td>290</td>
<td>61 (6.4 %)</td>
<td>163 (17 %)</td>
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</table>
Support to investigation

INVESTIGATORS NETWORKS
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**Early phase / experimental medicine**:

- Clinical Investigation Centres
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Franco-British bilateral symposium
CEntre National de Gestion des Essais de Produits de Santé

- Public/Private partnership
- Objective to reinforce recruitment in industry-sponsored trials
- 21 Disease-oriented networks of investigators
- Clinical research assistants in University Hospitals in all regions
EUROPEAN INFRASTRUCTURES
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Franco-British bilateral symposium
ECRIN National Hub

Institution

New national hub
French Clinical Research Infrastructure Network

Prof. Olivier RASCOL (Toulouse)

Investments for the future (Presidential Plan 2010)
Rationale

- Gathers the major stakeholders involved in clinical research in France
- Fills the gaps in clinical research tools – and not duplicates - in order to maintain the attractiveness of France in the European competition
- French hub to ECRIN
Objectives

• Platform and single hub open to both sponsors and investigators for improving the French competitiveness in three major fields:
  1. Large and complex multicentre trials
  2. Early phases industrial trials (big pharma, start-up, biotech)
  3. European projects, coordinated by France or extended to France

• Infrastructures
  1. Disease-specific research networks
     – Highly focused
     – Methodology, investigation, recruitment
     – Linked to translational research
     – Able to apply to European calls
  2. Distributed services platforms
     – Approached by both sponsors and investigators
     – Services "à la carte"
BBMRI-ERIC

51 research institutes
285 biobanks
31 countries
Coordination: Austria
France: 50 biobanks + 2 WP

Preliminary phase: 2008-2010
ERIC : 2013
BIOBANQUES encompasses 72 Centres with collections 600 research teams Investments for the future (Presidential Plan 2010)
ACADEMIC RESEARCH FUNDING

Major academic calls for clinical research
## Projects

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<tr>
<th>Source</th>
<th>Programme</th>
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<td>Soutien aux Technologies Innovantes et Coûteuses</td>
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<td>Inserm/Clinical Translational Research</td>
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## Infrastructures

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<tr>
<td></td>
<td><em>Ministry of research (Biobanques)</em></td>
<td>17 / 10yr</td>
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Conclusions

• Experienced investigators
• Sophisticated infrastructures
• Numerous resources

But

• Multiple layers
• Numerous lines of financial support
• Fragmented, separated, dispersed, sometimes redundant resources
END