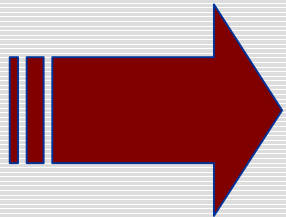


CeNGEPS (*National Centre for the Management of Health Product Trials*)

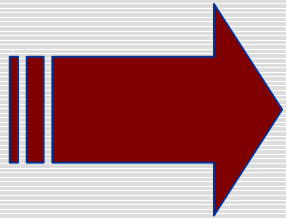
A Public/Private Partnership



CeNGEPS, a collective encompassing:



Strategic role of medical research in maintaining clinical trials in France



Difficulties encountered by operators and investigators (*increasing complexity, cost of treatment, medical demographics, 35h ...*)

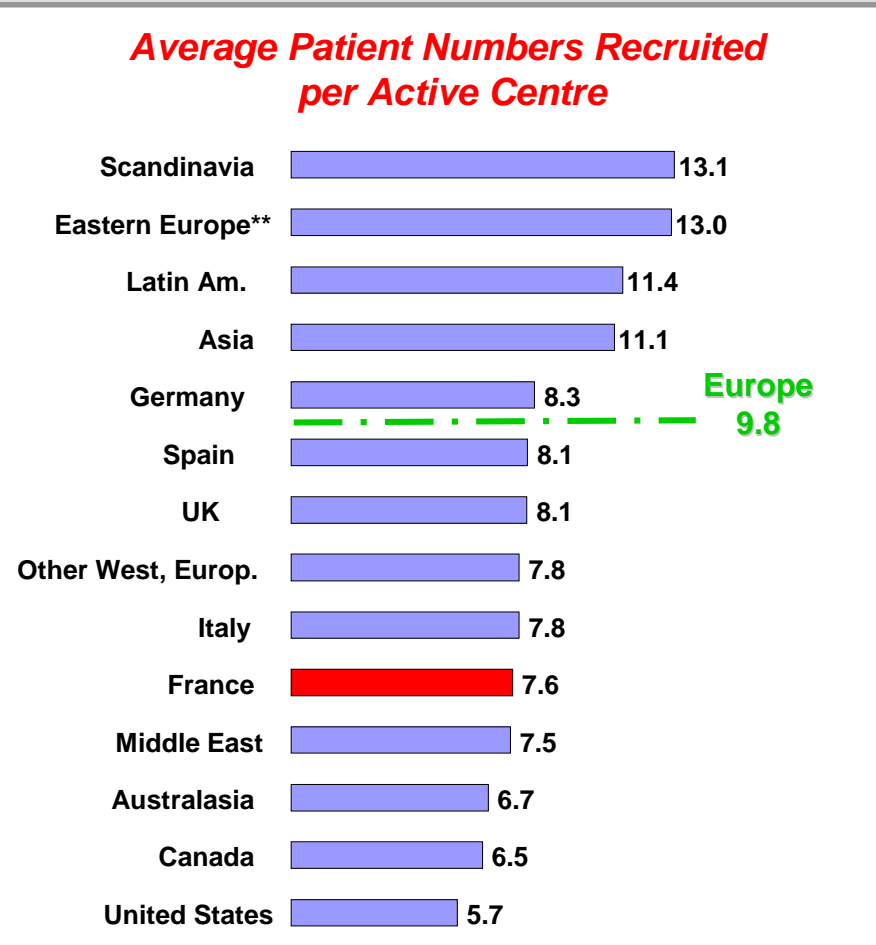
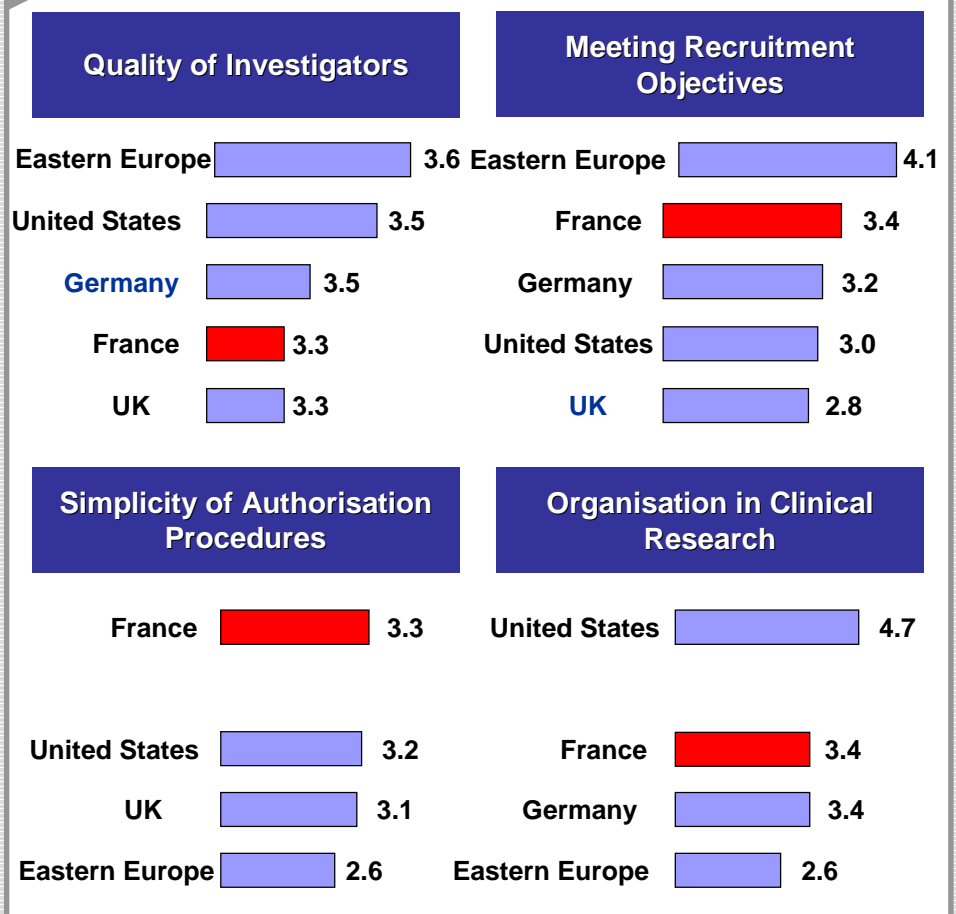
CeNGEPS: United to Strengthen Clinical Research in France

2008

Clinical Research in France

Strengths

Weaknesses



Extract from a survey on the attractive position of France in International Clinical Research (survey assessed in 2008 by Leem, French Pharmaceutical companies) Published in *Thérapie* 2008 Sept-Oct; 63 (5): 345-357

CeNGEPS, a bringing together of major clinical research operators in France

Public Associate Members **51%**

49% Private Associate Members



DIRC Est
6%



DIRC Grand Ouest
6%



DIRC Ile-de-France
6%



DIRC Nord Ouest
6%



DIRC Rhône Alpes Auvergne
6%



DIRC Sud Méditerranée
6%



DIRC Sud Ouest Outre Mer
6%

Inserm

Institut national de la santé et de la recherche médicale

Inserm
9%



French Pharmaceutical Companies Association

4 Associated Partners

- French Agency for the Safety of Medical Products (AFSSAPS)
- Hospital Federation of France (FHF)
- National Federation of French Cancer Centres (FNCLCC)
- French Association of University Presidents Group for Research (ACPUR)

* DIRC : Inter-regional Clinical Research Commissions

CeNGEPS : A Common Objective and Dedicated Resources



Objective : « Recruit More People, More Quickly and More Efficiently » for Industrial Clinical Trials

More efficient organisation of Industrial Clinical Trials:
3 criteria:

- Facilitate and speed up the setting-up of clinical trials
- Increase inclusions numbers and percentages
- Provide quicker results



CeNGEPS resources : One tax paid by pharmaceutical companies on their turnover (10 million Euro/year)

"CeNGEPS"



What action must be taken to support industrial sponsors of clinical trials?

5 Actions



« **Industrial Clinical Trial** » points of contact in inter-regional clinical research centres and medical centres



Human resources to support investigators



Support for a national clinical investigation network



Harmonise and rationalise procedures to shorten set-up time of clinical trials



Promote clinical research to public authorities, professionals and citizens

Professional representatives ready to assist industrial sponsors in the 7 Inter-Regional Clinical Research Centres (DIRC)

DIRC Ile de France

Dr Jean-Louis PETIT

jean-louis.petit@sls.aphp.fr

01 40 27 57 22

DIRC Nord Ouest

Mariam PETROSYAN

m-petrosyan@chru-lille.fr

03 20 44 67 37

DIRC Grand Ouest

Camille BERNEUR-MORISSEAU

camille.berneur@chu-nantes.fr

02 53 48 28 97

DIRC Sud Ouest Outre Mer

Eric DONOIS

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05 57 82 08 48

DIRC Est

- Carmen JOUANNEAU

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03 83 65 66 14

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03 88 11 62 71

DIRC Rhône Alpes Auvergne

Dr Marie-Claire MAZE

marie-claire.maze@chu-lyon.fr

04 72 11 51 81

DIRC Sud Méditerranée

Katia DEMEY

katia.solier@ap-hm.fr

04 91 38 11 51



"CeNGEPS"



- Supports investigators
- Structures investigation networks

160 CeNGEPS TECs working for investigators: what mission?

Main mission: to evaluate inclusion capacities and facilitate inclusion

- ↳ Screening of patients to be included in trials on the basis of inclusion/exclusion criteria, investigation centre's active-file and current protocols
- ↳ Attendance at trial set-up meetings with industrial sponsors
- ↳ Coordination and management of identified patients (initial call, appointment, file retrieval...)

« **CeNGEPS** » TECs are different from « **investigation** » TECs who, for their part, are responsible for the logistical side of clinical trials, and who are financed by the industrial sponsor.

A national network of 18 specialist investigation centres

Top specializations

- Infectious diseases/Vaccinology
- Neurosciences/Alzheimer's
- Psychiatry
- Cancer research : lymphoma, sarcoma, gynaecology / breasts, chest, early trials
- Cardiology/Thrombosis
- Paediatrics
- Nutrition/Diabetic studies
- Inflammatory diseases of the digestive tract



**More than
50 positions (ETP)
to Coordinate and Structure:**
Doctors and Clinical Study Technicians,
Project Managers,
Clinical Research Nurses...



Organisational Priorities

- Nationwide
- Reactivate dormant active-files
⇒ Hospital Centres
- Practice/Hospital ⇒ Chronic diseases

18 investigation networks supported by CeNGEPS (1)



Access to a pool of highly qualified investigators and an extensive patient database via a national point of contact

Network Name	Pathology	Coordinators	Contact
CeNGEPS Alzheimer	Neurosciences Alzheimer's	Pr Bruno VELLAS - Dr Pierre-Jean OUSSET / CHU Toulouse	vellas.b@chu-toulouse.fr
EDDH	Cardiology and psychiatry	Pr Raymund SCHWAN - Pr Faïez ZANNAD / CHU Nancy	contact@eddh.eu
GICIPI	Psychiatry	Dr Joël GAILLEDREAU / Elancourt	joel.gailledreau@gicipi.com
CNCHG	Cardiology	Dr Loïc BELLE / CH Annecy	cnchg@ch-annecy.fr
GIRC Thrombose France	Thrombosis	Pr Hervé DECOUSUS / CHU Saint-Etienne	laure.panei@chu-st-etienne.fr
RCP	Paediatrics	Pr Evelyne JACQZ-AIGRAIN / APHP - CIC Robert Debré	florence.emmanuel@rdb.aphp.fr
RIPPS	Paediatrics	Pr Gérard PONS / APHP - Dr Behrouz KASSAI / HCL	info@ripss.eu
CRICS	Intensive Care Sepsis and Infectious Diseases	Dr Bruno FRANCOIS / CHU LIMOGES	secretariat.cic@chu-limoges.fr

18 investigation networks supported by CeNGEPS (2)

Network Name	Pathology	Coordinators	Contact
MICI	Chronic inflammatory diseases of the intestine	Pr Christian LIBERSA - Pr Jean-Frédéric COLOMBEL / CHU Lille	clibera@chru-lille.fr
REIVAC	Vaccinology	Dr Odile LAUNAY / APHP - CIC Cochin	samira.chaalal@cch.aphp.fr
CNRH RA	Nutrition and Metabolic Diseases	Pr Martine LAVILLE / HCL	martine.laville@chu-lyon.fr
GOFEDI	Diabetes	Pr Michel KREMPF – Dr Lucy CHAILLOUS / CHU Nantes	michel.krempf@univ-nantes.fr
NADIS	Infectious Diseases (HIV, HCV, HBV)	Pr Pierre DELLAMONICA - Dr Pascal PUGLIESE / CHU Nice	pugliese.p@chu-nice.fr
GFPC	Chest Cancer	Dr Pierre FOURNEL / Institut de Cancérologie de la Loire - Pr Christos CHOUAID / APHP	christos.chouaid@sat.aphp.fr
IFTC	Chest Cancer	Pr Bernard MILLERON / APHP - Franck MORIN	franck.morin@ifct.fr
GEP	Early Trials Group Cancerology	Dr Véronique DIERAS / Institut Curie	veronique.dieras@curie.net
GELA-GELARC	Adult Lymphomas	Pr Bertrand COIFFIER / HCL – Pascal DESCHASEAUX	pascal.deschaseaux@gelarc.org
GSF-GETO	Sarcoma	Pr Florence DUFFAUD / APHM – Pr Jean-Yves BLAY / Centre Léon Bérard Lyon	fduffaud@ap-hm.fr
ARCAGY-GINECO	Gynaecological and Breast Cancer	Pr Eric PUJADE-LAURAIN / APHP – Bénédicte VOTAN	bvotan@arcagy.org

"CeNGEPS"



**Standardizes and
Rationalizes Procedures
to Shorten Clinical Trial
Set up Times**

Several standardized documents at national level

Agreements between industrial clinical trial sponsors and hospitals

A national grid to calculate additional costs

AGREEMENT RELATIVE TO PROTOCOL
STUDY NUM. «N_AGREEMENT»/«year»

BETWEEN THE UNDERSIGNED

The (UNIVERSITY) HOSPITAL « ... », «ADDRESS », represented by its (General) Director Mr. « ... », hereinafter "the (U) H ",

ON ONE HAND

AND

The «SPONSOR AGREEMENT» laboratory having its registered office at «ADDRESS», represented by its (General) Director, «REPRESENTATIVE», hereinafter «the Sponsor»,

ON THE OTHER HAND,

IN VIEW OF

- the Public Health Code provisions,
- the decision fixing the rules of Good Clinical Practice,
- the agreement signed by the DIRC (Interregional Clinical Research Delegation) « ... », and the GIP (Public Interest Group) « CeNGEPS »(National Centre for management of healthcare product trials), the « ... »
- the approval, certificates and documents necessary for carrying out the trial, which are presented by the (university) medical centre.

RECITALS

The sponsor has taken the initiative to carry out medical study called:
«NAME_OF_PROTOCOL»

It is stipulated that «TITRE» «Investigator» has declared to be acting as investigator and is prepared to direct and supervise the execution of said research,

JUN 2008 Page 1

National financial scale for clinical trials with industrial sponsors (in public hospitals) - July 2008

Nature of additional costs relative to biomedical research quoted in reference	Fixed costs per protocol	Number of procedures per patient	Variable costs per patient		Total for X patients
			Listed price of procedure, cost or number of procedures	Total cost per patient	
Administrative fixed costs (1)	€ 305		X		
Fixed cost for research implementation meeting (2)	€ 250				
Medical procedures:					
Fixed medical costs; information; consent (3)		1 hour of medical time			
Follow-up consultation(s) (depending on nomenclature)		X			
Other technical/medical procedures in addition to patients' usual treatment:					
Biological procedures		X	Sum of listed prices in B		
Nursing procedures (4)		X	Sum of listed prices for standard nursing procedures		
Imaging procedures (scans, MRI, scintigraphy etc.)		X	Sum of CCAM listed prices (common classification of medical procedures)		
Misc. procedures (electrocardiogram, function exploration etc.)		X	Sum of CCAM listed prices (common classification of medical procedures) *		
Unclassified paramedical time: (5)					
Nursing time (in excess of standard practice)			Based on hourly rate, ¼ hr registered nurse time (average rate: €30.50/hour)		
Technical time (centrifugation, aliquoting, sending tube)			Based on hourly rate, ¼ hr technician time (average rate: €28.20/hour)		
Additional clinical research technician time			Based on hourly rate (average rate: €28.20/hour)		
Fixed hospitalisation costs:					

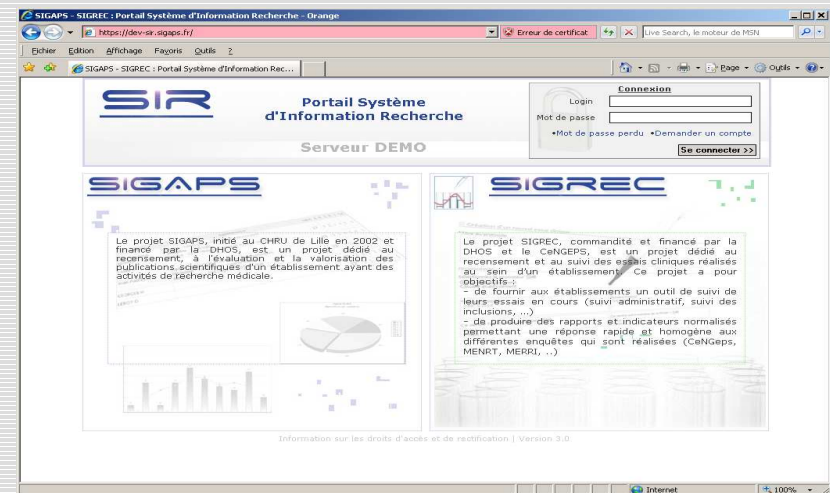
Objective : to reduce negotiation time

« SIGREC » a national hospital database to manage and follow up inclusions

- From manuals and logbooks to a national database
- Partnership between CeNGEPS and the Ministry of Health (DHOS)
SIGREC « a research and clinical trial information management system»
- Present in 80 health centres with the highest level of clinical research activity (29 University Hospitals, 20 Cancer Centres ...)

Digitalize (1)
Automate (2)
Standardize (3)

...



Objectives : Facilitate, Speed up and availability of reliable data

"CeNGEPS"



**Promotes Clinical Trials
to Professionals and the
Public**

www.cengeps.fr an information site for research professionals

Free access to an information database
(www.cengeps.fr)

- Clinical Investigation Networks Directory
→ 88 networks (ratings/specialisations)
- Information section on clinical research training

The screenshot displays the CeNGEPS website interface. At the top left is the CeNGEPS logo and name, with the full name 'Centre National de Gestion des Essais de Produits de Santé' below it. A search bar with 'Rechercher...' and an 'ok' button is present. Below the search bar is a navigation menu with 'English access' and a UK flag icon. The main content area is titled 'Investigation networks' and features a yellow banner with the text 'INVESTIGATION NETWORKS'. A sidebar on the left lists navigation options: 'Le GIP Cengeps', 'Les actions du CeNGEPS', 'Les inter-régions de Recherche Clinique', 'Les Annuaires' (with sub-links for 'Les réseaux d'investigation', 'Formation à la Recherche Clinique', and 'Investigation networks'), 'Documentation', 'Liens externes', 'Contactez-nous', and 'Extranet du CeNGEPS'. The main content area includes a section for 'Invest in France Agency' with a logo and text describing its role. Below this is a section titled 'GIP CENGEPs : AN INITIATIVE FOR MORE EFFECTIVE CLINICAL RESEARCH IN FRANCE' with an objective statement and a paragraph about the organization's mission. At the bottom, there is a search filter section with two dropdown menus labeled 'network name' and 'medical subject', both set to '--Select--', and an 'ok' button.

« *notre-recherche-clinique.fr* », launch of a website aimed at the general public in 2010

**Taking part in clinical trials,
an act of civic duty**



Two aims for this clinical research information site:

- Inform patients and healthy volunteers, in a simple and direct way of the objectives, risks and opportunities of clinical research.
- Facilitate inclusions by putting sponsors and investigators in touch with patients and healthy volunteers.

CeNGEPS (*National Centre for the Management of Health Product Trials*)

A Public/Private Partnership Group

