



LES ENTREPRISES DE LA
RECHERCHE CLINIQUE

WHY FRANCE ?

Strength and power of France in clinical
research
Know-how and expertise of French CROs

Summary

1. Business Processes Enablers
2. Operational excellence channel
3. Medical excellence channel
4. France, an EU leader in healthcare

The logo for AFCROs features the text "AFCROs" in a white, sans-serif font. The letters are contained within a white, stylized arc that curves over the top and under the bottom of the text. The background is a solid blue color.

AFCROs

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1. BUSINESS PROCESSES ENABLERS

French bashing

- + French are slow!
- + French don't meet schedule!
- + French don't meet enrolment targets!



FAKE
NEWS

Business Processes Enablers

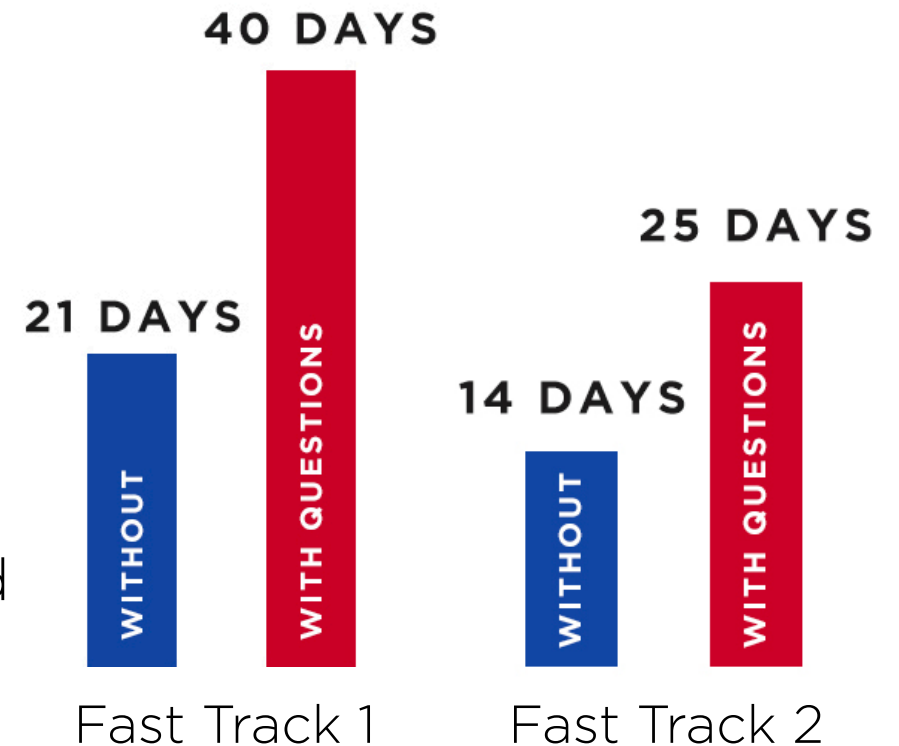
Fast Track process for Clinical Trials Authorizations

- + One competent Regulatory Authority (ANSM) and One Central Ethic Committee (CPP)
- + Dedicated ANSM Units and Dedicated CPPs
- + Accelerated process for clinical trials authorizations on medicinal product (Fast Track)
- + E-mails exchanges between ANSM /CPP /Sponsors /CROs
- + Very favourable scheduling and experts support

Business Processes Enablers

Fast Track Process / ANSM

- + **Fast Track 1** : Innovative treatments and clinical trials with complex design
- + Maximum 21 days without question and 40 days when questions
- + **Fast Track 2** : Drugs already known to ANSM
- + Maximum 14 days without questions and 25 days when questions (medicinal product) or 60 days for Advanced Therapy Medicinal Products (ATMPs)



Business Processes Enablers

ANSM uses experts' advices

- + Dedicated unit for early phase(s) clinical trials (except for pilot phases/EU regulation 536-2014)
- + Dedicated Units for each pathology
- + Expertise for medicinal products, medicinal devices and cosmetics
- + Special unit to advise start-ups and on processes for advanced therapies

Business Processes Enablers

Fast Track and Expertise: CPP

- + Dedicated CPPs for clinical trials on:
 - + Phase I,
 - + Paediatrics,
 - + Imaging,
 - + Cell and Genetics Therapies,
 - + Oncology,
 - + Assisted procreation,
 - + Genetics

- + Possible Fast Track: see case of Covid-19 clinical trials
- + Around 7 Days for Approval

Business Processes Enablers

Coordination optimization actions by ANSM

- + Pilot phase in France to implement EU clinical trials regulation: for example
 - + Medicinal products (EU 2014/536)
 - + Medical devices (EU 2017/745)
- + Coordination between all French stakeholders (ANSM/ CPP/Clinical Units/Sponsors/CROs)

Business Processes Enablers

Hospital Single Trial Agreement

- + One single agreement for all public hospitals trials signed by the coordinating Institution after budget approval
- + Agreement replicated and no budget discussion for the other hospitals (Associated institutions)
 - + *Time saving in terms of signoff by hospitals*
 - + *Very favourable time gain to begin multicentric studies*

Business Processes Enablers

Personal Data Compliance / GDPR

- + No need to ask for French Data Protection Authority (CNIL) for approval for each clinical study because of general Commitments to Compliance (MRx)
- + Compliance with GDPR is a legal obligation in France
- + France is a leader within EUCROF for the design of the European Code of Conduct. French CNIL is the reference body.

Business Processes Enablers

Temporary Authorizations for Use (1)

- + Innovated program initiated by France in 1994, A TAU is a special procedure for patients who have no available alternative treatment access to medicines with no marketing authorization (MA) in France.
- + ANSM delivers TAUs under the following conditions:
 - + medicines designed to treat, prevent or diagnose serious or rare diseases,
 - + when there is no suitable treatment available on the market,
 - + the effectiveness and safe use of the medicine are assumed and the start of treatment cannot be delayed.

Business Processes Enablers

Temporary Authorizations for Use (2)

- + Patient Temporary Authorizations for Use (TAUn), i.e. granted for a specific named patient,
 - + 5,642 patients included covered in 2018
- + Cohort Temporary Authorization for Use (TAUc)
 - + 15,987 patients included covered in 2018
- + Specific route possible for early access of innovative medicines since 1994

Business Processes Enablers

French Tax Credit for R&D Expenses (CIR)(1)

- + To promote R&D activities, French fiscal administration allows a 30% tax credit for R&D expenses subject to specific qualifications:
 - + Beneficiaries
 - + Process
 - + Deductible expenses

Business Processes Enablers

CIR - Beneficiaries and Process (2)

- + All companies subject to French corporate tax
- + No shareholder should control more 25% of another company benefiting from CIR
- + A special filing needs to be completed linked to the corporate tax declaration
- + The credit applies to the corporate tax for the civil year of the expenses. The credit may be cashed for small businesses such as start-ups, which is usually a significant financial help

Business Processes Enablers

CIR - Deductible Expenses (3)

- + R&D expenses related to phase I to III clinical studies in EEC are deductible
- + Depreciation of installations and equipment dedicated to R&D
- + Personnel expenses for researchers and technicians (personnel expenses for newly recruited PhDs are accounted x 2 for 2 years)

Business Processes Enablers

CIR - Deductible Expenses (4)

- + Billings of CROs registered with the French R&D Ministry limited to 30% of other deductible expenses
- + Expenses related to contract with public R&D institutions are accounted X 2 (hospital expenses & patient expenses)
- + Intellectual property expenses

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2. OPERATIONAL EXCELLENCE CHANNEL

Operational excellence channel

Attractiveness of France in Clinical Research

French operational excellence in clinical research is based on:

- + The largest network of dynamic and creative clinical research private companies (CRO) in Europe
- + A very active and renowned academic network
- + The most favourable environment in Europe

Operational excellence channel

The widest European clinical CRO offer

Numerous, specialized and dynamic clinical research professionals

- + More than 100 specialized CROs, working from Phases I-II-III to real world multicentric studies, offering international project management services or specialized sourcing,
- + The largest CRO representation in Europe : AFCROs (90 companies) main member of EUCROF¹
- + A dynamic pool of players in eHealth and dematerialized in clinical research
- + Access to a unique public database of health data (Système National des Données de Santé/Health Data Hub)
- + Upstream structures, preclinical CROs and research platforms, represented within the AFSSI (French association of services for innovation healthcare)

1) <https://www.eucrof.eu/members/directory>

Operational excellence channel

Academic Networks and KOL Investigators

- + Very active investigation public structures (Center of Clinical Investigation/CIC) and coordinated networks (F-CRIN¹/CNCR² ...)
- + Powerful public clinical research (European leader in number of trials) and partnering regularly with industry sponsors (Investigator Initiated Trials) and with CROs.
- + A recognized KOL pool in medicine and research

1) <https://www.fcrin.org/>

2) <https://www.cncr.fr/>



Operational excellence channel

The most favorable environment in Europe

- + Rigorous regulatory environment: French institutions and government authorities (CA, Ethics Committee) are very active and pilot projects at the European level (Data Privacy [GDPR], European regulation on clinical trials); coming to France ensuring that you are in a rigorous regulatory framework that complies with and minimizes risks
- + Upstream university training courses, internationally recognized specialized training courses (pharmacoepidemiology, Real World Data)
- + The strength of a network of dynamic and active company representatives (Digital Health / Syntec Numérique, #ChooseFrance...)
- + Active collaboration between all players: the State, public and private promoters, CROs

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3. MEDICAL EXCELLENCE CHANNEL

Medical excellence channel

The unique French Medical Excellence

- + A number of scientific academic societies in numerous fields, with a European or global leadership (international guidelines recommendations)
- + Many KOLs with an international reputation in various disease areas (oncology and onco-hematology, rare disease, CNS, cardiology, pneumology, infectiology...)
- + Many patient advocacy groups led by expert's patients
- + Many domains where France appears as a global leader in clinical research¹,
²: oncology and rare disease...

¹ <https://www.leem.org/publication/essais-cliniques-9eme-enquete-attractivite-de-la-france-pour-la-recherche-clinique-et>

² <https://www.leem.org/publication/lengagement-du-leem-pour-les-maladies-rares>

Medical excellence channel

Oncology : THE French expertise

- + 45% of industrial trials involving France concern oncology (versus 25% in Europe) *
- + 16 INCa-labelled centres for early-phase cancer research (CLIP²) **
- + Medical excellence in screening, diagnostic, treatment in oncology and hematology with a network of specialized public or private centers, such as « Centre de Lutte contre le Cancer », Institut Gustave Roussy (IGR) ...
- + Early access to innovative treatment thanks to early access programs (ATU)
- + Various cooperative groups (LYSA, GELA, FFCD...) with an international reputation and attractiveness

* <https://www.leem.org/publication/essais-cliniques-9eme-enquete-attractivite-de-la-france-pour-la-recherche-clinique-et>

** <https://www.e-cancer.fr/Professionnels-de-la-recherche/Recherche-clinique/Structuration-de-la-recherche-clinique/Les-CLIP2>

Medical excellence channel

Rare Disease : THE French expertise

- + 8 French coordination out of the 24 European Reference Network¹
- + 109 expertise centres in France for diagnostic and treatment of rare disease²
- + All patients addressed to specific reference centres => optimization of patient identification and recruitment
- + A dedicated website with a broader range of information:
<https://www.orpha.net/consor/cgi-bin/index.php?lng=FR>
Many charity initiatives for developing the research (AFMTELETHON...)
- + A clear governmental commitment for rare disease: 3rd plan for 2018-22³
- + A strong commitment from the pharmaceutical industry⁴

¹ https://ec.europa.eu/health/ern/networks_en

² https://www.orpha.net/consor/cgi-bin/Clinics_Filiere.php?lng=FR

³ <http://www.europlanproject.eu/NationalPlans?idMap=1>

⁴ <https://www.leem.org/publication/lengagement-du-leem-pour-les-maladies-rares>



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4. FRANCE, AN EU LEADER IN HEALTHCARE

France, an EU leader in healthcare

Key figures of France healthcare system



- + 67M inhabitants
- + Life expectancy: 82,52 years (85,7 women, 79,9 men)
- + Mortality: 9‰
- + Infant mortality: 3‰
- + demographic growth: +0,3%/year

Key figures (INSEE - source projections ONU (World Population Prospects 2019 revision))



- + 2nd EU market for human healthcare
- + +200B € of consumption of care and medical goods
- + 8,6% of GDP

France, an EU leader in healthcare

Key figures of France healthcare system (2)



- + 220 000 physicians:
 - + 30% hospital,
 - + 47% private practice,
 - + 11% mix,
 - + 12% others



- + +3 000 healthcare institutions: +1300 public / +1700 private
 - + 32 universities or regional hospital organizations representing 178 sites
 - + 240 psychiatric hospitals or centres for mental diseases
 - + 20 specialised hospitals for cancer diseases



- + +408 000 beds:
 - + +253 000 public beds
 - + +155 000 private beds

France, an EU leader in healthcare

Focus on few leading diseases management organization



+ Cancer

- + +400 000 new patients/year
- + 935 sites accredited for treatment



+ Rare diseases

- + +3M habitants suffering from rare diseases
- + 23 networks with 363 reference centres
- + + 1 700 competent centres

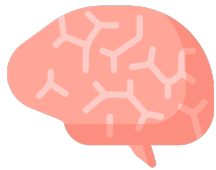


+ Infectiology (Pasteur's country)

- + Hepatitis B/C
- + HIV

France, an EU leader in healthcare

Focus on few leading diseases management organization (2)



+ Neurology and vascular

- + 135 neuro-vascular units for 150 000 stroke/year
- + 126 cognitive units for Alzheimer disease management
- + 25 experts centres for Parkinson disease



+ Pain management

- + 235 centres for chronic pain management
- + +227 000 patients treated/year

France, an EU leader in healthcare

#1 for medicines clinical trials

#1 for medical devices clinical trials

#1 for academic clinical trials

#4 for industrial clinical trials

+800 clinical trials initiated in France each year

Source: <https://clinicaltrials.gov> (data from 2019 - extraction 16 January 2020)

Conclusion

- + France is Europe 2nd healthcare market
- + Scientific and Medical environment in France is one of the world highest (notably oncology, rare diseases, infectious diseases)
- + Best quality / costs ratio and excellent execution standards / costs ratio of clinical trials in France.

Welcome to France!

