

YOU MAY ALSO COUNT ON US...

If you wish to have  
a legal representative  
in the European Union



FOVEA

CLINICAL RESEARCH



*"Let's write the Future together"*

## A legal representative in the European Union: Why?

European regulations require every foreign organisation that wishes to perform clinical trials in the EU to have a legal representative in one of the EU member states.

## Is conducting clinical trials in Europe an efficient choice?

- EU population totals 350 millions.
- Some EU member states are amongst the world leaders as to patients' recruitment capabilities.
- Clinical trials in Europe are a plus to obtain a marketing authorisation for the EU.
- With a local legal representation, setting up clinical trials in EU is rather simpler than doing so in North America; the timelines we shall set together will be adhered to.
- EU clinical trials' quality is on par with that of trials conducted in the US.
- A EU local representative will help you locating key European opinion leaders that may have irreplaceable expertise.

## FOVEA offers the whole service range you expect from a legal representative

- Guaranteeing compliance with European regulations.
- Ironing out regulatory, ethical or insurance issues that would delay you starting up studies throughout Europe.
- Having the relevant documents translated in local languages.
- Selecting for you, with you, centres that are able to perform world class, global clinical trials or "the centre" that is setting up a new trend.
- Dealing with clinical trial centres' administrative and contractual requirements.
- Taking care of European idiosyncrasies regarding medical data confidentiality.
- Complying with European regulations on pharmacovigilance.
- Finding suitable partners that may import and distribute experimental compounds to centres, wherever they are in the EU and whatever the dispatching procedures.
- Helping you set up a Data Safety Monitoring Committee with key opinion leaders.
- Ensuring that updated documents, according to ICH GCPs, are provided in due time to health authorities, IRB/IECs and investigators.
- Obtaining, if possible, an orphan drug status or a "fast track" registration process.



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*Since 1988, the FOVEA group provides services in the Health domain putting together teams of professionals to precisely meet your expectations. FOVEA manages about one hundred projects per year with a permanent concern for proactiveness, flexibility, rigour (ISO 9001 Quality certification - 21 CFR Part 11 compliance) and openness and is considered as one of the Leading organisations for Clinical Research.*

*FOVEA:  
The More you Dream,  
The Less Uncertain you  
Want to Be*

*A highly regarded partner of pharmaceutical industry, FOVEA is a global CRO that provides the following services:*

- *Design of Studies*
- *Data Management / Statistics (21 CFR Part 11 compliant)*
- *Medical Writing*
- *Monitoring*
- *Outsourcing*
- *On-line Studies Management*
- *Audit*

*Such services are provided for both:*

- *Pre-registration studies: phase I to phase III clinical trials.*
- *Post-registration studies whether they are purely medical (phase IV therapeutic trials) or medical with marketing relevance (epidemiological surveys, non interventional studies, quality-of-life studies or pharmacoeconomic trials).*

*We thank all the clients that,  
since 1988,  
put their trust in us*

- Abbott
- AstraZeneca
- Astellas
- Besins International
- BioAlliance Pharma
- Biocodex
- Bioprojet Pharma
- BMS
- Boehringer Ingelheim
- Bouchara-Recordati
- Brothier
- Chiesi
- Ela Medical
- Euros France
- Expanscience

- FNCLCC
- Galderma
- GE Healthcare
- Genzyme
- Gilead
- GlaxoSmithKline
- Grünenthal
- INCA
- Innate Pharma
- Ipsen
- Janssen-Cilag
- Johnson & Johnson
- Labcatal
- Leurquin Mediolanum
- LFB

- Medtronic
- Menarini
- Merck-Serono
- Novartis Pharma
- Novartis Santé Familiale
- Orphan Europe
- Pfizer
- Roche
- Sanofi-Aventis
- Schering-Plough
- Servier
- Solvay
- Solvay Pharmaceuticals
- Takeda
- 3M Santé
- Urogene
- Wyeth-Lederlé
- Zambon

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MEDICAL MARKET RESEARCH

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