

**CONTRACT RESEARCH ORGANISATION
FRANCE & WORLDWIDE**



QUALITY SYSTEM CERTIFIED ISO 9001

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A comprehensive know-how combining overall expertise with the flexibility of a company valuing the human dimension

FOVEA's specificity results from 3 competitive advantages:

- 1.** The flexibility of a small business combined to the organisation and thoroughness of a large company thanks to **outstanding Quality Management (ISO 9001)**.
- 2.** **Overall expertise** in the field of clinical studies, namely the capability to complement **the conception** and conduct of **pre-registration clinical studies** with the implementation and management of **medico-marketing studies** thanks to **a Marketing structure** present within the group.
- 3.** The ability to offer to the pharmaceutical industry **a genuine International structure** through a partnership agreement with one of the largest networks of international studies, whilst preserving the flexibility offered by a CRO valuing the human dimension (optimisation of the benefits/costs ratio).

ISO 9001 CERTIFICATION

A Quality System duly certified in order to offer you the best possible service

FOVEA obtained the ISO 9001 Certification of its Quality System on December 7th, 2000 thus becoming one the very first CROs certified in France.

- ***What are the fields of activities covered by this certification?***

The certification covers **the entire sphere of expertise in the Department of Clinical Studies at FOVEA**, namely:

- Conception, monitoring, data management, biometry of clinical studies before and after Registration
- Audit and related services in these fields of activities

- ***Why did we select the 9001 International Standard?***

The activities of FOVEA include a substantial amount of **documents conception for clinical studies** (protocols, case report forms...) as well as extensive computing investment development, especially for **on-line studies**. As a result, only the 9001 Standard was deemed to be appropriate and relevant since the 9002 Standard only covers those aspects linked to production.



- ***Which benefits does FOVEA gain from the ISO 9001 certification?***

This certification ensures permanent improvement and enhancement of FOVEA's performances and competitiveness, especially through:

- Injecting collective skills and talents within our overall methods which, up to now, were based on individual know-how
- Global improvement of all our projects generating improved quality, shorter delays, as well as increased productivity gains
- Improved unity among the various teams rallying around this project (*indeed, this certification is not an end in itself, but rather a new "launch"*) as well as improved channels of communications and exchanges between the various departments of our company
- Anticipating and preventing problems which might affect the quality of our services
- Better anticipation of the needs and requirements of our customers

- ***What does the ISO 9001 certification bring to FOVEA's customers?***

This certification guarantees to the customer that FOVEA is equipped with an internally-acknowledged, superlative system for organising and managing Quality, thus ensuring that every specific demands and requirements mentioned in the contract will all be met and implemented. Indeed, FOVEA officially pledges to be always in full control of all the various elements which might affect overall quality and agreed-upon deadlines throughout the on-going execution of a contracted project.

FOCUS ON OUR EXPERTISE

SERVICES

A global CRO offering a dual Medical and Marketing competence

Privileged partner of the Pharmaceutical Industry since 1988, FOVEA is a world-wide CRO that provides the following services:

- Conception of studies
- Biometry / Medical Writing
- Technical assistance
- Monitoring
- Management of on-line studies
- Audit

These services cover both:

- Pre-registration studies: therapeutic trials of phase I to III
- Post-registration studies, be they in the field of pure Medical Sciences (therapeutic trials of phase IV) or in the medico-marketing field (epidemiological surveys, observational studies, quality of life studies, pharmaco-economic studies)

THERAPEUTIC TRIALS

OF PHASE I TO IV

A successful therapeutic trial depends essentially on **the reliability of the data processed**.

This very reliability calls for **numerous skills** and implies:

- A rigorous Methodology
- A Protocol and Case Report Form that are both clear and well-structured
- Regular and thorough Monitoring
- Flawless Data Capture
- Exhaustive and interactive Data Management
- A standardised Statistical Analysis

Doubts must be raised about the validation and pertinence of the entire study if a single of these components happens to have been disregarded or neglected.

And it is precisely because we are acutely aware that, no matter the circumstances, these components simply cannot be dissociated from each other that we have set up **a multidisciplinary team** (*medical doctors, scientists, biostatisticians, data managers and computer scientists*).

This team works in concert to draw up and define each individual stage of the trial in order to identify (and thus eliminate) the pitfalls inherent to that stage, as well as any potential pitfalls that may show up during the later stages of the trial (*methodology unsuited to the goal defined in the protocol, case report form confusing for the investigator, poorly-defined assessment criteria...*).

We guarantee to apply the same rigour, thoroughness and working methods whether you entrust us with a complete or partial therapeutic trial.

MEDICO-MARKETING STUDIES

The following studies:

- Epidemiological Surveys
- Observational Studies
- Quality of Life Studies
- Pharmaco-economic Studies

Are all **post-registration studies** for which it is imperative to guarantee that the need originally defined is perfectly understood. It goes without saying that it is also crucial to offer unparalleled services. This requires **a dual "clinical" and "marketing" approach**: this is exactly what FOVEA is in a position to offer to the Sponsor since, within the same organization, the Department of "Clinical Studies" and the Department of "Marketing Studies" have always worked in synergy.

FOVEA is thus able to offer **3 competitive advantages**:

- The experience and knowledge of the methodologies and controls associated to Clinical Research
- The experience and knowledge from Marketing: feasibility studies, meeting arrangements, telemonitoring, document conception for study communications (*acronyms, logos, publications...*), contacts and relationships with Sales networks
- The experience and knowledge of data processing in large-scale studies

CONCEPTION OF STUDIES

It is precisely because we consider that the conception of a study is a vital, key-procedure which must only be entrusted to genuine professional persons that we selected **the ISO 9001 Certification** (*the 9002 Standard only covers those aspects linked to production*).

Each and every step of the conception process is subjected to **a Conception Review Board** validated, on both form and substance, by the Sponsor and the FOVEA Manager in charge of the project.

We are in a position to carry out **a comprehensive** conception of study (*protocol, case report form...*) or, equally as proficiently, **a more focused expertise**:

- Development of the study design
- Validation of the assessment criteria
- Compilation of the protocol's statistical section
- Determination of the sample size
- ...

BIOMETRY / MEDICAL WRITING

We offer the following Biometry services:

- Consultancy in statistical methodology: definition of the experimental plan, validation of the assessment criteria, determination of the sample size, setting up the randomisation
- Double data entry, coding (*international classifications*) and data Quality Control (*double data entry control and database audit*)
- Data Management: automated correction requests, audit-trail of data modifications
- Statistical analysis (*SAS software program*): exploratory and confirmatory analyses, meta-analyses
- Import and integration of external data under any format

We can also undertake the compilation in several languages of the following documents:

- Reports: Statistical, Clinical and Integrated within the ICH format
- Expert's reports
- Therapeutic memos and notes
- Investigator brochures
- Supports for medical communication: press articles, abstracts, posters

TECHNICAL ASSISTANCE

Whereas our competitors like to use wording such as "Outsourcing" or even "Control" we prefer to talk about Technical Assistance. Indeed, we consider Technical Assistance to be **a distinct, bone fide profession**, with its own specific functions, procedures and quality standards. Each person involved (*Data Entry Operator, Data Manager, Statistician, Clinical Research Associate, Project Leader*) retains **a strong, operational and hierarchical link with FOVEA through a referent**.

Thus, in the field of Monitoring, the Clinical Research Associate works under **a CRAs Manager** whose role is to:

- Provide technical assistance whenever the CRA is confronted with a problem
- Ensure that our service specifications are respected
- Validate all reporting elements sent to the Sponsor
- Pay co-monitoring visits on-site
- Control the regular updates of the Sponsor's Clinical Studies Monitoring program
- Execute a permanent training program with FOVEA's internal teams (*Biometry, Quality Assurance*) as well as external teams

These responsibilities are carried out on a daily basis, and not merely during a single, day-long meeting every month. Since **FOVEA** looks after and manages **the logistic aspects of the monitoring process**, the **Sponsor** is therefore free to concentrate on **the scientific and medical aspects of the study**.

MONITORING

We have learnt from experience that 3 elements are utterly inseparable from a successful Study Monitoring:

- **An effective co-ordination** assured by a Project Leader whose role is twofold: liaising between the FOVEA team involved in the study (*CRA's, Quality Assurance and, if necessary, the Biometry Department*) and the Sponsor (*hosting Sponsor /FOVEA meetings, compiling follow-up reports*), as well as managing the CRA's team assigned to the study (*co-monitoring visits, hosting internal meetings*)
- **Privileged relationships with investigators networks**, thus guaranteeing inclusion deadlines and the reliability of the collected data
- **The systematic implementation of a Quality Assurance Plan** whose aims are to define precisely and specifically the procedures, the sample forms and the reporting documents which will be used

We are in a position to manage **the complete or partial monitoring aspects of any study:**

- Execution of the preliminary feasibility study
- Recruitment of the co-ordinator and investigators (*hospital and town*)
- Management of regulatory procedures (*dossier for the Regulatory Authorities, information to Professional Bodies*) as well as administrative procedures (*investigators' contracts, hospital conventions...*)

- Organising and overseeing investigators' equipment (*constitution and delivery of the investigators' sample kits*)
- Preselection of the centres
- Implementation of the study (*organising and supervising investigators' meetings, initiation visits*)
- Monitoring of the study (*periodic visits and telephone contacts, telephone assistance through a toll-free number*)
- Dismantling and closing down the centres
- Management of serious adverse events
- Financial management of the study (*handling and settling investigators fees, handling and settling hospital cost overruns...*)

Furthermore, FOVEA has developed **Seven_ARC, an in-house software program specifically designed to monitor Clinical Trials**. Seven_ARC allows real-time editing of all the documents required to keep the Sponsor constantly informed and updated: anticipated schedule of visits, progress report of inclusions per centre, detailed reports of visits and telephone contacts, case report forms breakdown, compatibility between the therapeutic units per centre, budgetary breakdown per centre...

MANAGEMENT OF ON-LINE STUDIES

FOVEA has developed **e-fovea**, an in-house software programme specifically conceived to run and manage on-line studies. E-fovea has been designed so that it can be used by Sponsors and Investigators alike.

This **secured** tool **improves the quality of the Data Collecting process, optimises the Monitoring procedure** and thus **shortens the Data Management process** whilst **substantially reducing overall costs**.

The main benefits for the Investigator are:

- Easier and trouble-free data entry on the electronic CRF thanks to the on-line help permanently available
- Reduction of the time spent with the Monitor thanks to the improved data entry procedure
- Possibility to access and to view, in real time, general information about the study

The Sponsor will benefit from:

- Faster and amplified recruitment of investigators
- Instant access to the main results of his study
- Enhanced interactivity with the investigators
- Effortless and straightforward study management
- Guaranteed completion deadlines

AUDIT

FOVEA follows a **global approach** which combines **our technical competence** (*Conception of studies, Monitoring, Data Management, Statistics, Medical Writing*) with **our proven expertise of Quality Management**.

The services that we offer are based on two central themes:

- Audits
- Consultancy in Quality Management

• **Audits**

- Audits of phase I to IV clinical trials during every single stage of the process
- Systems Audits (*ISO 9000 Quality System, procedures*)
- Service providers Audits

• **Consultancy in Quality Management**

- Implementation of a Quality procedure:
 - . Assistance with methods recognition and analysis
 - . Assistance in determining the guiding elements in the methods in relation to quality
 - . Drawing up the appropriate documentation in relation to quality
 - . Implementation of Quality Management tools
- Guidance and assistance all along the Certification procedure under the ISO 9000 standards:
 - . Assistance with the conception of the quality manual
 - . Assistance with procedures implementation
 - . Audit prior to certification
- Training:
 - . Heightening staff sensibility to Quality
 - . Practical tutorial on the ISO 9000 standards
 - . Internal Quality Auditors

FIELDS OF GEOGRAPHICAL INTERVENTIONS

An international structure allowing the optimisation of the benefits/costs ratio

FOVEA signed a partnership agreement with one the largest international studies networks. FOVEA brings in the expertise of a CRO, whilst our partner provides an operational base in every concerned country. This alliance enables us to offer several kinds of additional logistical services:

- Local branch (providing, as and when needed: office space and facilities, telephone assistance through a toll-free number, a co-ordinator, translators, participation in the recruitment of local CRAs...)
- Preselection of investigators according to criteria defined by FOVEA and/or the Sponsor
- Logistical organisation of investigators meetings
- Implementation and management of every single logistical element (transport of patients and samples, liaison with the partners of the study [e.g. centralised laboratory]...)
- Supply management of therapeutic units and material to the centres

This organisation allows FOVEA to offer to the pharmaceutical industry a genuine international structure, whilst preserving the flexibility offered by a CRO valuing the human dimension. The ratio benefits/costs is thus optimised.

PUBLICATIONS

A policy of well-structured services in order to keep you continuously informed and up to date

Fovearc

The main aim of these publications is to examine, primarily through the testimonies and statements of professional people (industrialists, public companies, private partners), the various problems linked to the Conception and Management of Clinical Studies



Our Publications in Statistical Methodology

The primary aim of these publications is to present to the various professional people in the Medical and R&D Departments of the pharmaceutical industry some pragmatic and straightforward concepts to enable them to "decipher" the often esoteric language found in scientific publications and statistical sections of clinical studies protocols...



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