



Brochure

About The Company
Drug Development Strategy
Regulatory Affairs
Pharmacovigilance
Quality System & Audit
Training

*promoting science,
honoring life*

viglya[™]



The Company

Find out why Viglya is your strategic partner in drug development.

Viglya is a consulting firm which provides guidance to bio- and pharmaceutical companies in the area of life science, specializing in drug development strategy, regulatory affairs, and pharmacovigilance during all clinical phases and life cycle follow-up. We also provide related services, such as quality system implementation, auditing, and training.

Viglya is your company's multicultural partner with a global presence through our various partnerships within Europe and the United States. The company's quality services and results forge solid and long-term relationships with its stakeholders.

The brand name Viglya reflects the company's main interests: providing professional support in the area of life science; offering top quality, ethical services with enthusiasm; enriching professional relationships with global strategic thinking; and as a result, becoming a preferred partner to our clients.

Providing valuable, effective solutions

Viglya's mission is to provide the bio- and pharmaceutical industries with a strategic consultancy par excellence in drug development and product life cycle management. We work with rigor and precision to facilitate innovative and effective solutions that both enhance our stakeholders' potential for success and comply with regulatory requirements worldwide. Our ultimate objective is to protect public health and improve patient quality of life.

Being a strategic partner

Our vision is to be relied upon as a key partner for success on an international level, and to become a major collaborator in drug development and product life cycle management. We will achieve this by delivering the highest quality services in an efficient and timely fashion, and by building a strong relationship with our stakeholders.

The values that guide our daily activities

Excellence

In our relationship with our clients. We believe that quality interaction among our team, our business partners, and regulatory bodies builds solid and sustainable relationships that lead to outstanding results.

In our scientific work. We are committed to applying rigorous standards and methodologies to our work, and to continuously monitoring the complex and rapidly evolving regulatory environment, above and beyond our clients' expectations. Our ultimate goal is to achieve high standards of public health protection.

Adaptability

From our team. We are a team of talented professionals with global experience acquired in multinational bio- and pharmaceutical companies. We accurately interpret our customers' needs and offer a broad range of synergistic, high value, and customized services to fulfill them.

In our vision and strategic approach. We have a comprehensive knowledge of the global regulatory landscape and a clear understanding of its challenges. We work with efficiency and dedication in partnership with our clients to better assist them in reaching their business goals, by creating a sound strategy, adopting efficient processes, and leveraging available systems and technologies.

Passion and Commitment

To customer satisfaction. Our skilled and motivated team of professionals is passionate about life, our clients, and patients, and is committed to professional relationships that bring about innovation and customer satisfaction.

Worldwide Network for US Client



Worldwide Network for EU Client



- NCA: National Competent Authority
- LRA: Local Regulatory Agency
- Viglya's Worldwide Team of Experts

Partnership and Collaboration

Viglya was launched in early 2012 to serve the bio- and pharmaceutical industries in key aspects of drug development and product life cycle management. We are dedicated to becoming a key strategic partner in the area of life science and by working closely with our clients we offer our extensive expertise and profound knowledge of the international regulatory landscape as an extension of our client's internal teams. Viglya is passionate about its projects and takes pride in helping customers grow.

The Viglya team excels in working collaboratively. Our team of professionals is attuned to our client's unique needs and tailors its leadership, proactivity, and transparency to fit the client and business partner network. We work with experts located in different countries, mainly in Europe and the United States, to more efficiently and thoroughly provide the services of our organization.

Viglya is eager to establish both local and global partnerships. Our intention is to build rewarding collaborations that contribute to the success of our clients, while fulfilling the company's corporate values of Excellence, Adaptability, Passion, and Commitment.

...“I chose and developed my professional career driven by the desire to improve the lives of people beset by often incurable diseases. Science has much to contribute and every day is an opportunity to find new therapeutic solutions”.

*Marie-Dominique Mompas
Managing Director*

Responsibility

Viglya's commitment to its team and stakeholders includes achieving the company's business objectives in a sustainable and responsible manner, while respecting environmental resources and social values.

Viglya strives for success in the bio- and pharmaceutical sectors by acting in accordance with its corporate values of excellence, adaptability, passion, and commitment. Viglya also fulfills its corporate philosophy of building strong, successful, and lasting professional relationships.

Viglya considers itself a part of society and one of its objectives, as such, is to behave in a socially responsible manner. While commercial success is an objective, it is not our sole consideration. Furthermore, Viglya formulates long-term goals for our professional activity, decisions, and strategic alliances.

Drug Development Strategy Services

Viglya helps clients develop regulatory strategies that focus on discovering and rapidly building scientific evidence to support the safety and efficacy of compounds. We assist in identifying and addressing critical path issues that could delay development timelines, and we help define the hurdles to registration. We provide strategic guidance in marketing authorization applications (MAAs), clinical (efficacy and safety) summaries, overviews, and labeling development.

Viglya also assists with legal representation activities in Europe and provides full United States (U.S.) Agent services, including U.S. Investigational New Drug (IND) submission, negotiation, and maintenance.

Drug Development Strategy & Regulatory Input on Clinical Programs

- Strategic development and execution of comprehensive drug development programs based on the compound's Target Product Profile and the regulatory landscape.
- Strategic input on U.S. FDA meeting planning (pre-IND/IND, end-of-Phase I, II, III, and pre-New Drug Application (NDA) meetings); briefing documents preparation and review.
- Guidance in the preparation for European scientific advice (including European Medicines Agency [EMA] and national procedures): briefing documents preparation and review.
- Clinical Trial Application (CTA) and U.S. IND preparation, review and filing.
- Guidance in contract research organization (CRO) selection for individual clinical trials and for full clinical programs execution (CRO qualification and selection, Services Agreement review).
- CRO oversight (communication plans with milestone identification, technical plans, governance model).

- Preparation of presentations for Investigator Meetings and Scientific Advisory Boards.
- Review of charters for Data Safety Monitoring Boards, Adjudication Committees, Steering Committees (clinical programs). Participation in presentation generation and delivery.
- Assistance with drug registration processes both in the U.S. and in Europe:
 - Integrated Efficacy and Safety Summaries (ISE/ISS);
 - Clinical Efficacy and Clinical Safety Summaries (CSE/CSS);
 - Clinical Overview.
- Risk Evaluation and Mitigation Strategies (REMS) and Risk Management Programs (RMPs).

Creation of Product Information (Labeling) for Inclusion in Original U.S. NDA and MAA

- Development of initial U.S. Package Insert, European Summary of Product Characteristics (SPC), patient leaflet and other local product information documents based on data from product development, the most current labeling guidelines and regulations, product therapeutic areas, recent approvals, and regulatory trends.

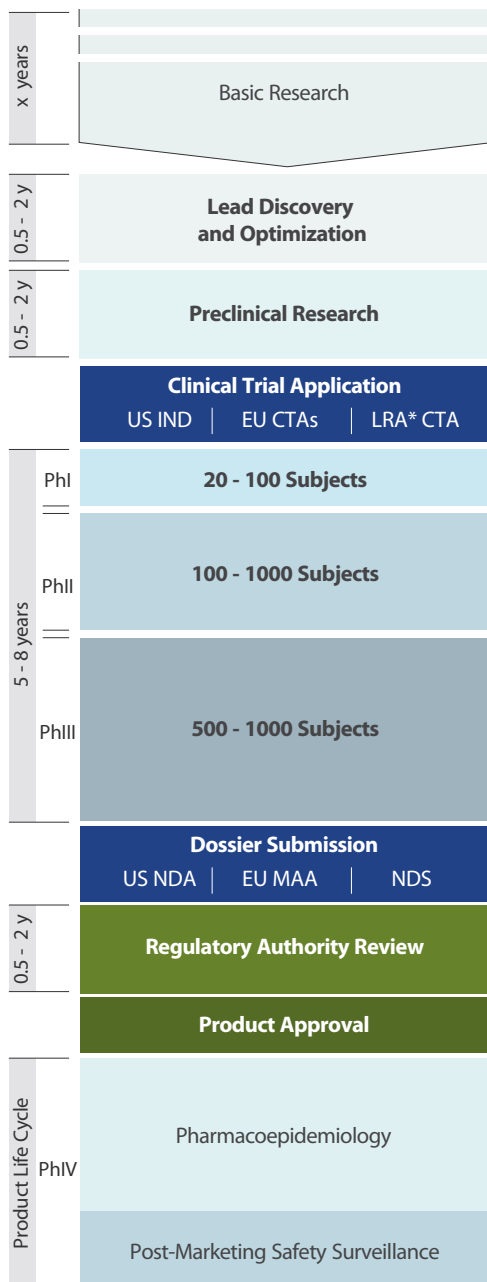
Due Diligence Activities

- Assistance in due diligence activities (European Union, U.S.) for products in all phases of development and commercialization:
 - Conduct of independent data assessment;
 - Assessment of the level of regulatory risk (serious non-compliance).
- Assistance in identification of opportunities for in-licensing and out-licensing.
- Identification of business partners for critical business functions, such as drug development, distribution, and co-marketing.



Have you decided on the best approach for conducting your clinical program globally?

Drug Development Process



LRA: Local Regulatory Authority
NDS: New Drug Submission in any country

Further Questions

- What are the key differentiating characteristics of this product versus competitor products in terms of target labeling?
- Is there a precedent for the indication and for the key claims being sought?
- Which currently available guidelines might impact the development program?
- When should meetings with health authorities occur and which key issues should be addressed at each meeting?
- What is the range of options available for registration (eg, fast-to-market with small initial indication followed by supplemental applications versus a broad claim up front)?
- Are any accelerated development or approval pathways applicable, such as Subpart H approval, fast track designation, or priority review?
- Are there opportunities for expanded market exclusivity via such regulatory mechanisms as pediatric exclusivity, orphan drug protection, and/or Waxman-Hatch exclusivity?
- Is there a need to influence health authorities and/or key opinion leaders to accept proposed study designs, endpoints, key claims? If so, what is the plan (who, when, how, what is the desired outcome)?
- What are the known regulatory risks for the program?
- What is the plan for global registration, if applicable? Simultaneous submission in Europe and in the United States? Or a key market first?

Regulatory Affairs Services

Are you thinking of implementing a new electronic document management system?

Viglya provides guidance in the implementation of document management and publishing systems, and assists in the development of regulatory submissions from both a scientific and technical perspective. Viglya also helps establish internal advertising and promotional regulatory processes.

Regulatory Submission

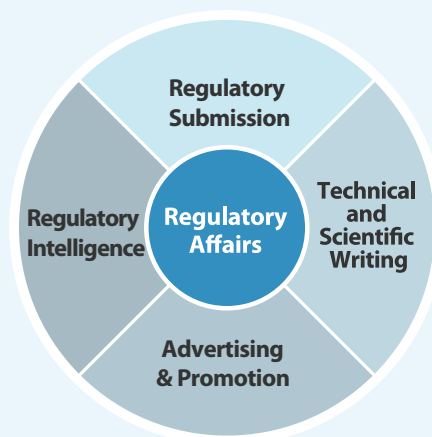
- Assistance in the implementation of electronic publishing and document management systems.
- Gap analysis and assessment of document management system and eCTD software application needs and requirements.
- Evaluation of various service providers, vendors and technologies.
- Oversight and/or implementation of the selected solution. Definition of system specifications. Assistance in system validation.
- Assistance in the compilation and management of submissions, in paper, eCTD, or Non-eCTD Electronic Submission (NEES) formats.
- Advice and assistance in managing the transition from paper to electronic document management and archiving, including legacy documents and submissions.

Regulatory and Scientific Writing

- Strategic writing of briefing documents (required for meetings with regulatory agencies), IND and CTAs, and clinical summaries and overviews included in registration dossiers.
- Document authoring, update, and review of regulatory submissions using company templates and style guides, or Viglya templates and style guide, to create submission-ready documents, such as:
 - Clinical: Protocols, Clinical Study Reports, Investigator's Brochures;
 - Regulatory: IND Annual Reports, NDA Reports;
 - Safety: Development Safety Update Reports (DSURs), PSURs;
 - Labeling: Core Data Sheet (CDS), Core Safety Information (CSI), local product information (eg, U.S. Package Insert, European SPC).
- Technical and scientific review and quality control of regulatory applications.

Advertising and Promotion

- Assistance in the definition and implementation of processes and procedures relevant to the creation, review, and approval of promotional and advertising materials. Authoring of policies and SOPs; training delivery.
- Strategic support in the elaboration of competitive and compliant promotional and communication materials.
- Regulatory review of promotional copies and publications to meet business objectives, while ensuring the necessary level of regulatory compliance, and adherence to client policies.



Regulatory Intelligence

- Monitoring of emerging trends, (draft) policies, regulations, and guidance that might impact and affect the client's products and business.
- Review, interpretation, and communication of the assessment of new regulatory requirements and guidelines specific to products and therapeutic areas. Analysis of the impact of changes on a compound's clinical development and life cycle management.
 - Review of Advisory Committee meetings material, Summary Basis of Approval (SBA), European Public Assessment Reports (EPAR), and newly released product labeling, to understand precedent regulatory actions and trends.

Further Questions

- *Do you need help in the scientific writing and compilation of your CTAs?*

Pharmacovigilance Services

Is there some area of pharmacovigilance where you lack resource or expertise?

Viglya provides a broad spectrum of drug safety services tailored to the needs and requirements of our clients. Our experts have years of experience developing innovative and highly-customizable solutions for the drug safety management of both investigational drugs and marketed products. We help manage the safety of the client's products with a regulatory-compliant and best-practices approach.

European Qualified Person at Pharmacovigilance (QPPV)

- European Economic Area (EEA) Qualified Person for Pharmacovigilance (& deputy QPPV).
- Establishment and maintenance of pharmacovigilance systems.

Local Pharmacovigilance Representative

- Local pharmacovigilance representative (eg, in Spain).
- Direct interaction with local regulators on pharmacovigilance and regulatory matters.
- Set up of local pharmacovigilance system (SOPs, etc.).

Pharmacovigilance System

- Definition of pharmacovigilance and quality systems.
- Guidance in defining an outsourcing strategy, qualification of service providers, oversight, and project management.
- Definition and implementation of an issue and crisis management process, communication channel, escalation process, and governance model.

Safety Solution & Case Management

- Guidance in identifying, assessing, and selecting a safety solution adapted to the client's organizational structure and product portfolio. Assistance with safety database validation (21CFR11) and implementation, and with safety data migration.
- Assistance in identifying the best provider for Individual Case Safety Report (ICSR) processing.
- Support with expedited E2B electronic reporting definition and testing, and EudraVigilance (EV) registration.
- Elaboration and testing of business continuity plans (eg, information technology system failure; disaster recovery; contingencies).

Medical Information Support

- Assistance with selecting provider for (24h) medical information for scientific information.

Pharmacovigilance Agreements with Third Parties

- Generation and maintenance of pharmacovigilance agreements.
- Establishment of clear communication channels and methods with partners.

Periodic Safety Update Reports (PSURs)

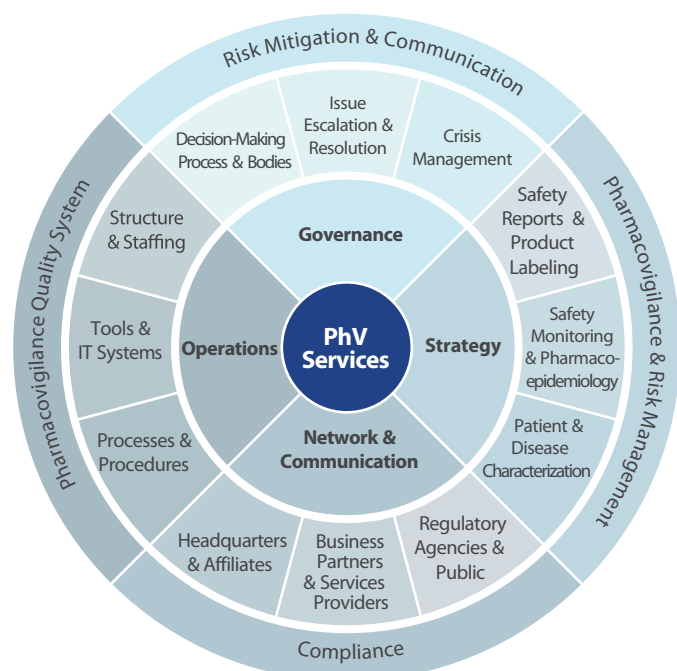
- Compilation, medical review, and submission of PSURs, addenda, and summary bridging reports.

Risk Management System

- Elaboration of RMP/REMS.
- Guidance in managing potential and identified risks.
- Assistance in defining pharmacovigilance actions, risk minimization and risk prevention strategies.
- Assistance with the implementation of the EU RMP at national levels.

Risk-Benefit Evaluation / Epidemiology

- Assistance with defining and implementing safety monitoring activities and epidemiology strategies during all phases of drug development, peri-approval stage, and product commercialization.
- Support in defining and implementing safety signal detection, investigation, and evaluation activities for marketed products.
- Assistance with selecting a CRO for the conduct of epidemiology and post-authorization safety studies.





Quality System & Audit Services

Are you well prepared for an upcoming pharmacovigilance inspection?

Viglya assists in designing and implementing a quality system that meets regulatory expectations (including the generation and streamlining of procedures and methodologies). Viglya helps clients prepare for upcoming internal and business partner audits and regulatory inspections to ensure their efficiency and success. Viglya also guides clients in developing Corrective and Preventive Action Plans (CAPAs) derived from audit findings.

Quality System

- Assessment, design, and management (control) of quality system for regulatory affairs and pharmacovigilance, based on the client's organizational structure and regulatory environment.
- Generation, review, and streamlining of company policies, SOPs and Working Instructions/Guidelines.
- Development of job descriptions and training programs.
- Establishment of performance metrics: identification and monitoring of key performance indicators to help measure a client's system performance and effectiveness.
- Definition of CAPAs related to findings identified during audits or inspections. Assistance with supervising the implementation of CAPAs.

Compliance Monitoring & Quality Control

- Definition and oversight of compliance against internal processes, regulatory requirements, contractual agreements, and privacy and data protection laws.
- Design of quality status reports. Proposal for quality and efficiency optimization. Advice on industry best practices.
- Assistance with ongoing monitoring of processes (internal and CRO/vendors) and deliverables (eg, ICSRs, PSURs, core labeling). Identification of process optimization and quality improvement. Documentation of deviations to the pharmacovigilance system.

Audits

- Elaboration of pharmacovigilance and regulatory audit programs.
- Performance of pre- and post- marketing systems audits worldwide.
- Pharmacovigilance system audits of the global function, the local offices, business partners, CROs, and third-party vendors.
- Definition, implementation and supervision of CAPAs; root cause analysis.

Regulatory Authority Inspection Preparation

- Conduct of mock inspections and inspection readiness exercises.
- Design and delivery of training in preparation for inspections, including logistics, interviews, and role play.
- Advice on inspection coordination and management activities.
- Advice on optimizing responses to inspection findings.

Quality System Definition

Structure	Processes & Procedures	Outcomes
Compliance Monitoring & Quality Contrd		
Initial and Continuous Training		

Quality System Contrd

Quality Assurance Audit Program
Audit & Inspection Readiness

Audit Steps



Training Services

*Are you looking for help on
developing a training program
for your new R&D staff?*

Today's rapidly changing global regulatory environment requires that the professionals of the bio- and pharmaceutical industries possess a strong foundation in pharmacovigilance. This demands ongoing, comprehensive, and up-to-date training and education. Viglya helps clients develop and implement customized corporate training plans that ensure teams acquire the adequate knowledge and develop the right competencies and attitudes to meet daily challenges successfully.

Training on Company Procedures

- Design of continuous training programs in pharmacovigilance and regulatory affairs.
- Generation and delivery of tailor-made, on-site training on drug development, pharmacovigilance, and regulatory affairs.
- Assistance with developing interactive workshops (remote training packages; training manuals).
- Assistance with developing (online) company-level pharmacovigilance training.
- Guidance and support in implementing online training based on client's internal processes, systems, and requirements.
- Assistance in the implementation of training tracking systems, training records management, and systems monitoring.

Training on Current Legislations and Guidelines (Europe, ICH, U.S.)

- Pharmacovigilance modular training for pharmacovigilance staff (all responsibility levels) and for non pharmacovigilance-staff: basic and in-depth trainings customized to the client's needs.
- Regulatory Affairs training: in depth or tailor-made training on key regulatory aspects of interest (eg, requirements for opening an IND in the U.S.).

Mentoring and Coaching of Staff

- Training, mentoring, and coaching of staff on specific regulatory and pharmacovigilance activities (budding EU QPPV, junior and senior staff) in support of professional development.

Example of Pharmacovigilance Course

- Introduction to Pharmacovigilance.
- Pharmacovigilance System.
- EMA and U.S. FDA requirements.
- Volume 9A / "Good Pharmacovigilance Practices".
- ICH guidelines, CIOMS group.
- ICSR processing and management.
- MedDRA coding.
- Medical Review and Causality Assessment.
- Expedited reporting.
- Electronic submission.
- Medical Information.
- Literature Review.
- PSUR.
- DSUR.
- RMP and REMS.
- Safety Monitoring in Clinical Programs.
- Safety Signal Detection.
- Pharmacoepidemiology.
- Labeling: Investigator's Brochure, DCSI, CCDS, CCSI.
- European Qualified Person for Pharmacovigilance.
- Quality System.
- Preparation for Pharmacovigilance Inspection.
- Pharmacovigilance Agreements.

