phetairos
Trusted partner for
pharma & life sciences

An introduction to Phetairos Product Development – Clinical and Regulatory (PDCR) Services

"In an ever changing and competitive environment, Phetairos Product Development - Clinical and Regulatory expertise helps our clients to design and implement an optimum clinical and regulatory pathway."

Phetairos – Overview

OUR ETHOS

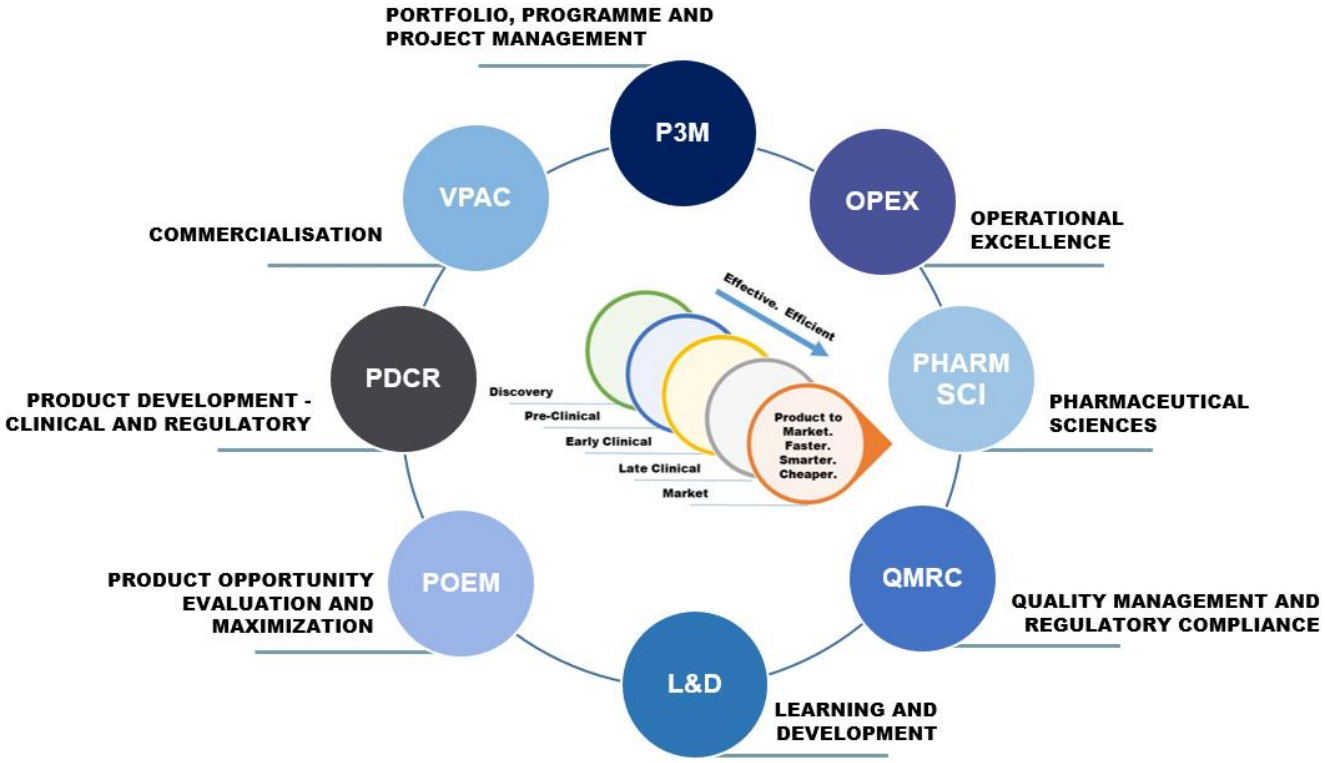
We are "committed to delivery through collaboration": Phetairos is dedicated to consistent delivery of successful client outcomes through collaboration, quality assurance, flexibility, cultural alignment, transparency and knowledge sharing.

WHO WE ARE

We are a group of world-class BioPharmaceutical subject matter professionals, who put best practice to work for our clients, designing integrated innovative solutions - on both product and organizational levels - for the complexities of a constantly changing life sciences ecosystem & marketplace. The calibre of people we allocate to our clients' projects, people with 20 and 30 years of hands-on experience in their subject matter, combined to a project team covering multiple subject matters depending on our client's specific issues and situation complexity, is truly unique in the industry. Our unbiased approach enables our clients to realize their business goals by minimizing risk, raising product / portfolio value, saving cost and reducing time to patient.

WHAT WE DO – OUR SERVICES

With our unique fusion of expertise in the full range of disciplines across the product lifecycle, we help releasing the full potential of our client's products, organisations and people.



We provide strategic decision making, planning, and management as well as optimised resourcing to execute strategic programmes and projects. We operate as a lean structure without organisational overhead and pass on the benefits created directly to our clients with payment linked to successful outcomes achieved against time, quality and cost based deliverable

Product Development – Clinical and Regulatory (PDCR) Services

Phetairos Product Development - Clinical and Regulatory (PDCR) practice is comprised of leading healthcare industry subject matter experts with a proven and well-established record of achievement across all phases of product development in a broad range of therapeutic areas. We have a passion for clinical development and a mastery of local and global regulatory issues, landscapes and guidelines.

We provide:

- strategic and operational input to start-up, biotechnology and pharmaceutical companies and other organisations engaged in the discovery, research and development of potential new therapeutic agents.
- close collaboration with clients to achieve targeted solutions and has flexibility to work for individual clients or as part of a multi-disciplinary teams.

Below is an overview of our PDCR services:

REGULATORY	*CLINICAL*	*CLINICAL PROJECT*	*BIOSTATISTICS*	*MEDICAL WRITING*	*QA & COMPLIANCE*
Liaise with HA, Regulatory Bodies, Advisory Boards & Patient	**Global Clinical Development Strategy**	**Project Management Plan Development**	**Design & Prepare Pre/Post-Approval & Marketing Clinical**	**Clinical Study Reports, Safety Narratives,**	**Design GLP/GCP Compliance Strategies**
Target Regulatory Strategies & Development Plans	**Design & Implement Clinical Trial Program**	**Recruitment Strategy & Projections**	**Statistical Analysis Plans**	**Pediatric Investigational Plans**	**Perform GLP/GCP Audits**
Regulatory Intelligence	**Study Design**	**Liaison with KOLs and ACROs**	**Clinical Efficacy & Safety Summaries**	**Orphan Medicinal Product**	**Training for Inspection**
Consulting Services	**Assess Trial & Programme Feasibility**	**Steering Committee, CEC and DMC Management**	**Data Mining & Predictive Analytics, Biomarkers Identification & Safety Signal Detection**	**Scientific Advisory Board Reports**	**Plan & Follow-up Corrective Actions**
Medicinal Product Registration	**Assess Clinical Pharmacolog**	**Vendor Selection and Management**	**Development Programmin**	**Grant Applications for Public/Private**	**Assess GLP-Compliant Developmen**
Package Insert	**Review Scientific**	**Risk Assessment**			
Safety & Pharmacovigilanc					

REGULATORY SERVICES

- Provision of Strategic Global Regulatory Advice
  - Regulatory Strategy
  - Clinical Development Planning
  - Strategic Planning
  - Compliance to global regulatory requirement
- Provision of Regulatory Intelligence and regulatory trend updates
- Creation of high-quality regulatory documents such as but not limited to
  - Orphan Medicinal Product Designation
  - Investigational Medicinal Product Dossiers
  - Clinical Trial/IND applications
  - Paediatric Investigation Plans
  - Briefing Books
  - Module 2 Overviews
- Review and risk assessment of all Documents supporting Clinical Trial Applications, Briefing Books, Marketing Authorisation applications and Post-approval follow up submissions as well as device documentation
- Interface with Regulatory Authorities as Sponsor contact, Health Authority lead and/or team preparation for Health Authority meetings. Support for Notified Body meetings and Health Technology Assessments
- Support for Consult with health authorities, regulatory agencies, advisory boards and patient groups
- Target regulatory strategies and development plans
- Regulatory intelligence
- Regulatory consulting services: Preparation and maintenance of clinical trial submissions (clinical trial application and investigational new drug application) and Support of marketing authorisation regulatory license documentation throughout Life Cycle
- Common technical document sections and modules for new product applications and line extensions
- Maintenance of compliance of investigational and registered products through their lifecycle
- Medicinal product registration
- Package insert adaptation
- Regulatory adverse event and serious adverse event reporting
- Manufacture registration
- Report compilation and publication
- Proof reading, rewriting and editorial support
- Support for legal representation

CLINICAL SERVICES

- Global clinical development strategy
  - Provide the global clinical development strategy for a medicinal product
  - Provide biomarker strategy and disease stratification approaches
- Design and implement clinical trial programme
  - Provide long-term goals
  - Incorporate adaptive trial designs where required
- Study design
  - Design studies from concept through to full protocol (from safety to confirmatory testing) to include production of investigator brochures, informed consent forms and other supportive study documents
  - Design prospective non-interventional studies, registries, post-marketing studies and retrospective research to meet safety mandates, health outcome/economics, payer support and compelling publications
- Assess trial and programme feasibility
  - Assess global/site feasibility for clinical trials and drug development programmes
- Assess clinical pharmacology studies
- Review scientific proposals
- Other clinical services
  - Scientific advisory board formation, operational charter and minutes
  - Managerial oversight of the clinical group implementing clinical studies
  - Medical monitoring including data safety review
  - Training on study specifications

CLINICAL PROJECT MANAGEMENT SERVICES

- Project management plan development
    - Provide expertise and best in class project management practices to include all project planning
    - Development of comprehensive plans (timeline management, communication, budget management, risk management, resource management, quality and clinical monitoring)
    - Plans tailored to your needs and to also cover the scope of a full-service project from site selection to the final report including regulatory, clinical, data management, safety, biostatistics and medical report services
- Recruitment strategy and projections
    - Provide a full recruitment strategy including projections of first patient in and last patient out as part of the overall project delivery
- Liaison with Key Opinion Leaders, Steering Committee, Central Ethics Committee and Data Management Committee
    - Selection and management of steering, clinical endpoint and data monitoring committees
    - Charter writing and meeting management to meet project timelines and expectations
- Vendor selection and management
    - Vendor services sourced may include Clinical Research Organisations (CROs), drug supplies, depots, translators, imaging laboratories, electrocardiogram providers, patient and travel reimbursement agencies
    - Advise on sourcing strategy development to support drug development portfolio and business objectives
    - Conduct supply market and vendor profiling
    - Shortlist potential vendors
    - Cost model development and pricing benchmarking
    - Conduct due diligence
        - Regulatory Risk: to confirm vendor's appropriateness for the tasks being outsourced
        - Delivery Risk: to confirm vendor's experience and skills to perform specific tasks
        - Quality Risk: to define vendor's procedures and processes
        - Cost risk: to define what need can correctly increase risk of change order
    - Advise or lead agreement negotiation
    - Agreement implementation
    - Vendor performance management
    - Arbitration and dispute resolution
- Project Risk Assessment
    - Identify Critical Project Risks, primarily categories associated with project endpoints and patient safety
    - Assess measures of Impact, Probability and Detectability in order to generate a risk score for each category
    - Plan a comprehensive clinical trial risk mitigation strategy

BIOSTATISTICS SERVICES

- Design and prepare clinical trials, post-approval studies and marketing initiatives
- Statistical analysis plans including tables, figures and listing shells
- Summaries of clinical efficacy and safety
- Planning, conduct and reporting of Interim, final, post-hoc analyses and meta-analyses
- Data mining and predictive analytics, biomarkers identification and safety signal detection
- Development programming and independent quality control and validation SAS programming

MEDICAL WRITING SERVICES

- Clinical study reports, safety narratives, clinical study protocols and investigator brochures
- Paediatric investigational plans, scientific advice documents, orphan designation applications and all other health authority contacts
- Scientific advisory board reports
- Poster presentations and slide decks
- Grant applications for public and private funding

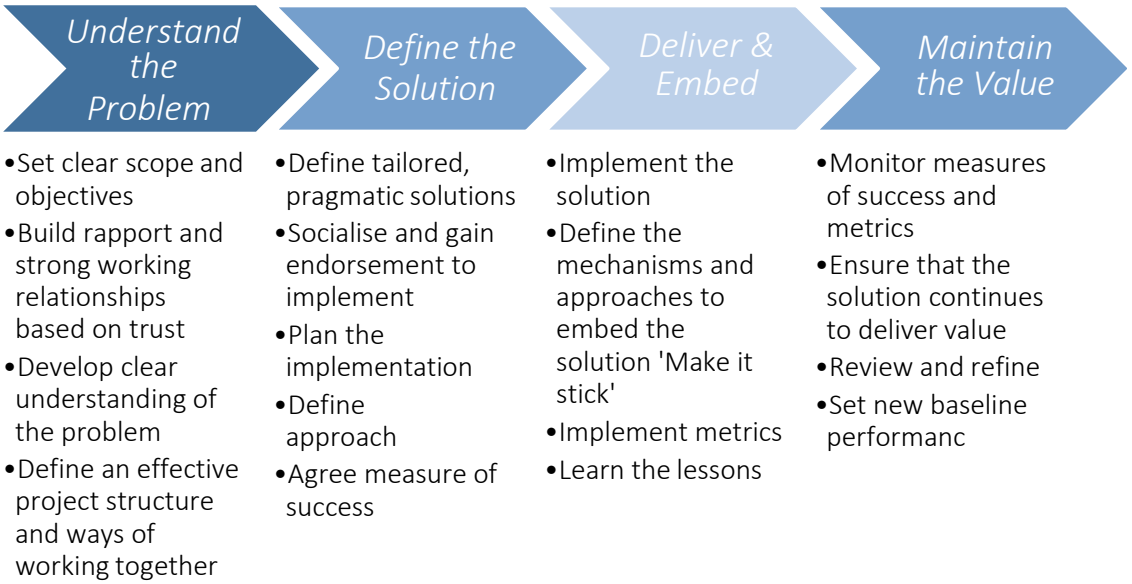
QUALITY ASSURANCE AND COMPLIANCE SERVICES

- Design Good Laboratory Practice (GLP) and GCP compliance strategies to minimise safety risks to research subjects
- Perform GLP and GCP audits, including ad-hoc advice and inspection readiness training and plan corrective actions and follow-up to complete the actions
- Assess GLP-compliant development, supplied by contract research organisations, including validated pharmacokinetic, immunogenicity, pharmacodynamic (biomarkers) and cell-based assays

HOW WILL WE OPERATE ON YOUR PROJECT?

PHETAIROS can rapidly assemble teams and ramp-up resources to integrate into the client's organisation to provide expertise and hands-on capacity to support client's needs.

We create tailored solutions and seamless integration to fit your product, needs and goals. These are not quick fixes. We aim to embed solutions that will have a lasting impact on your organisation.



PHETAIROS CASE STUDIES

The following examples illustrate the experience and value that the PHETAIROS PDCR team can bring to our clients:

PHETAIROS HELPED A VIRTUAL BIOTECH COMPANY WITH NO CLINICAL OPERATIONS EXPERTISE SELECT A SERVICE PROVIDER FIT FOR PURPOSE TO DELIVER THEIR PHASE I STUDY

- Situation: A virtual UK-based biotech company with limited knowledge of GCP requirements needed to source a service provider qualified to deliver their Phase I study with a potential biologic analgesic. They were unaware of the regulatory risks associated with lack of compliance, delivery, quality and cost when insufficient due diligence was ensured through a non-rigorous selection and capability assessment process.
- Services: PHETAIROS work with the client to define the critical success criteria for the selection of a fit for purpose phase I unit. They acted as the outsourcing department of the client developing a request for proposal versus the study requirements and critical criteria. They worked with four full-service, MHRA-accredited phase I service providers and guided the client through a robust selection process including capabilities assessment and risk assessment to enable the identification of the most appropriate candidate.
- Result: A Master Services Agreement was developed with the selected phase I unit. Contracts including key success criteria were developed for study start up and for full-service delivery.

URGENTLY NEEDED SPECIALIST WITH REGULATORY EXPERTISE AND ADVICE FACILITATES REGULATORY APPROVAL WITHIN ORIGINAL TIMELINES

- Situation: A mid-sized pharmaceutical company was in the middle of a de-centralised regulatory procedure when it suddenly needed additional expertise to complete the on-going procedure. There was a need to respond to questions, finalise the labelling and manage an unexpected complication due to a member state having raised national health concerns at the end of the procedure.
- Services: PHETAIROS partnered with the various departments of the client to prepare, review and submit the responses.
- Result: The client was provided with satisfactory responses which were handled in time through personal contacts with the health authorities. The company obtained the approval of the medicinal product in the EU according to their original regulatory plan.

EXPERT WRITING OF REGULATORY PROCESS DOCUMENTS FACILITATED CREATION OF A NEW AND EFFICIENT REGULATORY AFFAIRS GROUP

- Situation: A large leading pharmaceutical company with no experience in the Food and Drug Administration arena needing to setup a new efficient and strong US regulatory team to help it expand.
- Services: PHETAIROS provided a team of experts to guide the development of more than 35 processes relating to Food and Drug Administration regulations and guidelines. Process mapping allowed process documents to be easily understood by new staff and thus increased process compliance.
- Processes provided a simple and deliberate approach to learning Food and Drug Administration regulations and guidelines and to easily understand language and instructions on regulatory requirements. Process-related report templates, tracking systems, forms and checklists allowed staff to immediately reap process benefits each time they were applied. Training of new staff was improved.

- Results: A large team of experts wrote processes which allowed clear roles and responsibilities to be defined that fed into the correct set-up on regulatory affairs team. The company received a full suite of process documents which new staff could be immediately trained on.

PHETAIROS HELPED A SMALL PHARMACEUTICAL COMPANY ACTIVE IN RARE DISEASES TO RAPIDLY ANSWER REGULATORY QUESTIONS AND ACHIEVE DRUG SUBMISSION ON SCHEDULE

- Situation: A small European pharmaceutical company had filed an application for the treatment of a rare disease and had received a large number of clinical pharmacology (pharmacokinetics and drug interactions) questions from the centralised European Medicines Agency, rapporteur and co-rapporteur in the critical assessment reports. The responses to these questions were extremely time-critical to the overall filing and finalisation of the summary of product characteristics and the company realised they required additional clinical pharmacology expertise to complete these responses.
- Services: PHETAIROS provided clinical pharmacology expertise and, partnering with the client to prepare, review and submit the answers to the questions in a much contracted time.
- Result: The client was provided with timely responses to the extensive number of questions, which enabled the responses and the submission to be completed on schedule.

LARGE-SCALE LABELLING SUPPORT TO SIGNIFICANTLY INCREASE COMPLIANCE

- Situation: A large leading pharmaceutical company needing to set-up a new centralised team to manage labelling changes and compliance.
- Services: PHETAIROS provided labelling support for 22 markets in the European Medicines Agency region. We worked with each local contact to fully collect local requirements, understand product portfolio and organise priorities into a label submission plan. Current systems were used to manage changes in labelling, including updates and tracking of progress. Processes were initiated and implemented to increase compliance by integrating current approaches and joining forces with the submissions and artwork team to optimise an end-to-end process.
- Results: A strategic plan was implemented to bring each market from noncompliance to a business as usual model. Compliance increased from 20% to 90% in 6 months, with a similar strategic plan for other regions. PHETAIROS was requested to work on other departmental projects to help increase compliance and enhance processes.

A VALUABLE LARGE CLINICAL STUDY WAS RAPIDLY DEVELOPED AND COMPLETED

- Situation: A subsidiary of a large pharmaceutical company intended to launch a product for vaginal thrush. Marketing approval had been obtained but there were few data on product use in a real world setting.
- Services: A non-comparative study involving nearly 2000 patients was set-up in 4 months in 200 general practices and completed within a further 3 months and the results analysed. The whole project from initial set-up to report for publication was completed in 9 months.
- Results: The study provided excellent efficacy and safety data, a publication, early experience among target General Practitioners and useful additional information in subsequent marketing materials.

REGULATORY MEDICAL WRITING WITH A TRACK RECORD OF CLINICAL STUDY REPORT WRITING

- Situation: A large pharmaceutical company developed a novel antiretroviral drug to treat human immunodeficiency virus. There was a need for a Lead Writer to author all clinical study reports for programme from Phase 1 to Phase 3.
- Services: Inputs were obtained from the drug development clinical team; all 15 clinical study reports were reported in a timely fashion from Phase 1 and Phase 2 through to complex, first pivotal Phase 3 study; and as key member of the drug development team, obtained approval and sign-off by Clinical Lead for regulatory submission.
- Results: the company gained rapid Food and Drug Administration approval which led to sales of £143 million in 2013.

FEASIBILITY ASSESSMENT FOR OUTSOURCING OF A REGULATORY AFFAIRS ACTIVITY

- Situation: The leadership team had identified a large operational/routine noncore process that they wanted to outsource against a target of cost savings and efficiency increase.
- Services: A feasibility study was initiated with the consultant ensuring the process demonstrated rigor and aligned to best practice business outsourcing practices. Using the output from the process mapping, the consultant led a market & external vendor delivery capability assessment resulting in a risk/benefit assessment of outsourcing the identified process.
- Result: The feasibility assessment showed that the outsourcing of the end to end process could achieve the targets, but the risk/benefit assessment conducted by the consultant identified a number of key risks and barriers that would undermine a successful outsource. The Leadership Team accepted the recommendation to improve the efficiency of the internal process before outsourcing should be considered. The consultant helped the client avoid outsourcing a process that was not outsource ready and avoiding a potentially costly failure.

CONTACT FOR FURTHER INFORMATION

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