



An introduction to Phetairos Commercialisation Services

“Achieving a marketing approval is just one of the hurdles when defining the potential success of the development of a product. Maximising market potential and commercial success of a company’s products, that’s where we come in.”

Phetairos – Overview

OUR ETHOS

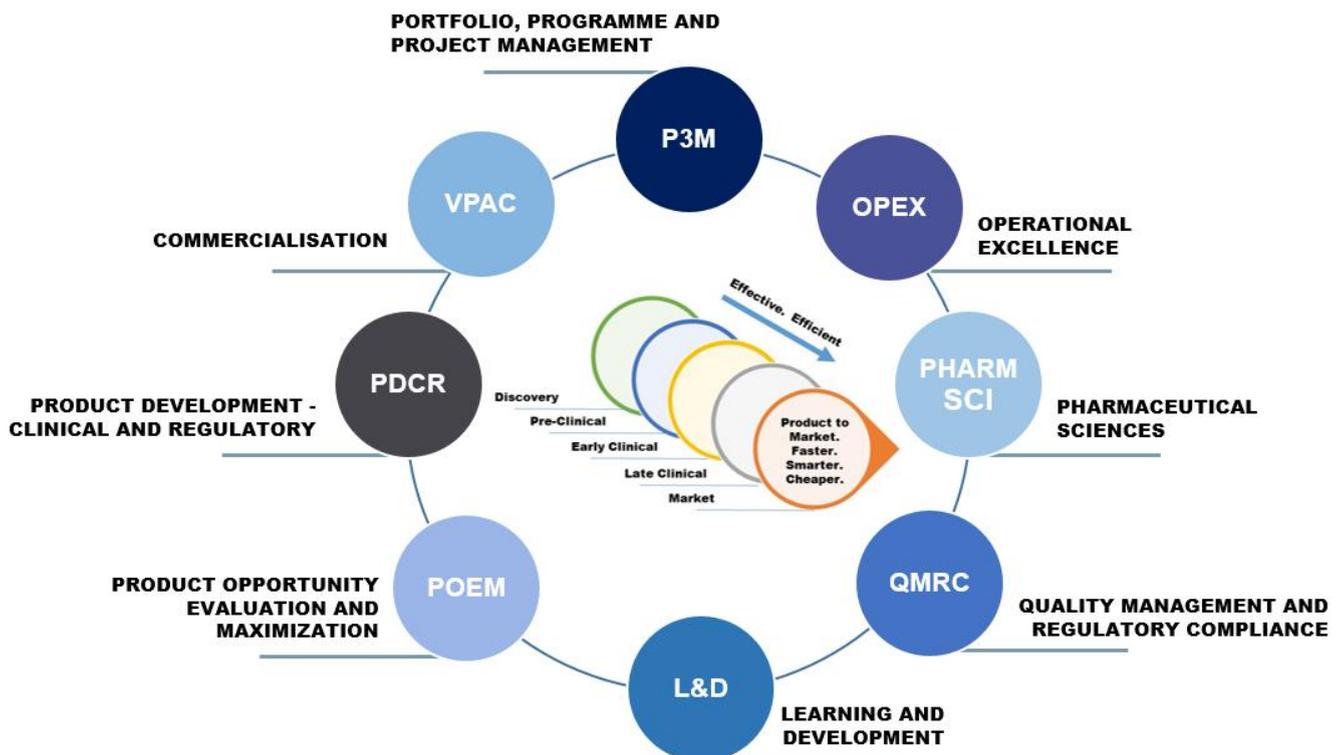
We are “committed to delivery through collaboration”: Phetairos is dedicated to consistent delivery of successful client outcomes through collaboration, quality assurance, flexibility, cultural alignment, transparency and knowledge sharing.

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 deliverables.

Commercialisation Services

SERVICES

Achieving a marketing approval is just one of the hurdles when defining the potential success of the development of a product. Phetairos offers the services around the following areas maximising market potential and commercial success (by phase).

Phase I-II

- Review of the competitive landscape and identification of outcome parameters, such as quality of life measures, required for later HTA submissions
- Develop early pricing models based on initial data which can be reiterated with increasing data
- Identification of required goals in terms of efficacy and safety to assist in go/no go decision making.

Preparation for Launch (Phase IIIa/b):

- Refinement of the launch Target Product Claims, brand vision, market positioning and value story.
- Upgrading the commercial S.W.O.T., risk assessment, source of business assessment, sales forecast and commercial go/no-go criteria
- Overall commercial launch strategy & value proposition enhancement.
- KOL Mapping to inform decisions on study sites.
- Development of an evidence-based communications strategy with healthcare providers and payer audiences
- Publications benchmarking and strategy
- Ensuring clear differentiated product vision defined for key markets that reflects on-going trials, real world evidence and personalised medicine opportunities.
- Study comparator option assessment and determination in for key markets.
- Identification of value-critical payers and ensuring a Phase III program addresses their needs.
- Target patient population clarification, then confirming prescribers and payers can easily identify these patients.
- Alignment of the Phase III program and reimbursement dossier to the Target Product Profile and Target Product Claims, the brand vision and market positioning.
- Global reimbursement dossier plan validation.
- Life cycle management (Phase IIIb, IV and PASS/PAES) opportunity assessment and design.

Launch Phase:

- Launch plan and activity maps ensuring activity aligns to strategic drivers of success. Covering landscape analysis to inform the launch plans, marketing, medical, sales, opinion leaders, congresses, and pricing and market access.
- Marketing programs including; promotional guides, objection handlers, training programs and manuals, core slide sets, source files, clinical reprints, advert content, e-marketing, media programs, market research tracking and insight.
- Internal and external communication objectives, strategies, plans and bespoke target audience programs. Including advisory boards, publications educational platforms and meetings. Long term and/or short term.
- Development of Local and Global Value Dossiers and Updates.
- Assembly of Formulary Inclusion Evidence, or Formulary Kits.
- Drug Monograph.

Life Cycle Management (Phase IIIb, IV and PASS/PAES) through to peak sales:

- Development of continuing marketing plans to increase share and sales growth.
- Ensuring connecting global and local commercialisation plans.
- Identifying barriers and developing strategies to unlock sources of business.
- Life cycle development for new formulations, indications, geographies.
- Brand portfolio management and prioritisation to maximise returns.
- Cost effective commercialisation to improve margins in later stages of the brand's life cycle.

CASE STUDIES

The following examples by phase illustrate the experience and value that PHETAIROS can bring to its clients (by phase):

Case Study: Health economic models

- Situation: A blue-chip pharmaceutical company had developed an antifungal drug for use in a variety of conditions ranging from simple thrush to managing a deadly form of fungal meningitis in patients with HIV. The cost of the drug was relatively high compared to available comparators.
- Service: a series of health economic models was set up to provide support for formulary acceptance.
- Result: The models were later widely used by the sales force for gaining acceptance.

Case Studies supporting a broad range of market entry and commercialisation activities

- Startup Biotech company - Guidance on how to achieve optimal pricing and positive reimbursement in selected EU countries.
- Startup MedTech company – support for a government affairs campaign accompanying a commercial access strategy to enter the UK NHS market.
- Small pharmaceutical company - Technical report providing details of patient rights to treatment in England and Scotland including the processes and steps required to gain reimbursement in the absence of positive HTA guidance.
- Small pharmaceutical company – Developing evidence and a summary dossier to support a price rise under the UK PPRS scheme based on re-introduction of an oncology product.
- Medium sized pharmaceutical company - Technical report outlining how PPRS disputes should be handled based on real life cases including a DoH strategy guide and draft letters to practically secure successful resolution of a dispute.
- Medium sized Diagnostics Company – Market access and lobbying activity, overcoming NHS barriers due to budget silos and disincentives to adopt new diagnostics with clear and evidence based quality improvements and cost savings to the NHS.
- Medium sized biotech company - Review and adaptation of a health economic model to achieve positive NICE guidance based on identification of an optimal ICER which NICE were likely to, and did approve.
- Medium sized consultancy - Evidence based review of examples of NHS service redesign. This was used to inform various clients on optimal NHS engagement strategies based on different models of field force structure and delivery of supporting materials.
- Large pharmaceutical company - Review of an SMC submission and guidance on how to adapt this to achieve positive guidance from the NCPE in the Republic of Ireland.

Case Study: Turning around the sales of a mature brand

- Situation: Mature brand with plateauing sales but several years' patent life.
- Service: A 5-month project, comprising comprehensive market assessment and gap analysis against a best practice checklist to identify the top growth potential regions and countries. Supported engagement

of global team with local brand management in target territories to agree investment plans to drive a rapid increase in sales and improve margins.

- Result: Client actions implemented: a new sales team deployed in US, increased sales and marketing investment in 4 major EU countries, renegotiation of API supplier terms to improve margins. Sales responded quickly with 25 % year on year growth 1% margin improvement.

Case study: Launching a Companion Diagnostic

- Situation: A client with a portfolio of GI products including a leading brand of a treatment for Ulcerative Colitis (UC) wanted to gain rapid access to payer organisations in the UK. The UK National Health Service had only just restructured itself and access to these decision makers was extremely hard to gain. One key issue was that primary care physicians in the UK are not confident in diagnosing UC and often unnecessarily refer patients with Irritable Bowel Syndrome for expensive endoscopy. Research found that nearly a third of patients presenting for endoscopy had IBS and that this was costing over £200 million annually.
- Service: In order to give the client's sales force a greater chance of gaining access to the payers, a diagnostic test that could be used in primary care was sourced and then launched alongside the existing product portfolio. The core proposition was the chance for each payer to save nearly £1 million a year from their referrals budget – a significant and attractive offering. In addition to the savings in avoidable referrals arising from the use of this diagnostic, the company's reps were able to present the savings accruing from the use of their UC treatment with a view to gaining formulary listing and increased usage. This amounted to a further annual saving of over £200,000.
- Result: Access to the payers was considerably greater than that of the competition. The end result was that the lead brand gained formulary listing by 73% of the payer organisations within 5 months, of which half had listed the product as first-line. The market share of the brand increased in a market that had been otherwise stable. The launch of the diagnostic test was proposed to the client and then sourced, negotiated and launched whilst the consultant was working for the client as the interim Divisional Head. The process from proposal to launch was four months.

Case study: Communication strategy for a Biosimilar mAb

- Situation: A non-European company without an established presence in Europe or the Americas was intending to launch a biosimilar into Europe and the US. In anticipation of the first product launch, the company needed to prepare the global markets and show their product to be an effective and safe biosimilar for use in all the indications approved for the originating product. The company also recognised that it had to establish its credibility in order to broaden regulatory and reimbursement pathways for increased patient access.
- Service: This meant helping them become more outward facing, to hold critical dialogues with relevant authorities, communicating scientific and clinical data and the ability to comply with the authorities. The company was introduced to leading clinical, patient advocacy, payer and policy opinion formers, to create strategic relationships, provide feedback on stakeholder expectations and unmet needs and help define company positioning.
- Result: The company's and the world's, first biosimilar monoclonal antibody was approved by EMA for the same indications as previously licensed product and has been successfully launched.

HOW DO PHETAIROS ADD VALUE?

Solutions tailored to your needs:

- Best-in-class knowledge, skills and experience to guide projects, programmes and portfolios to deliver their full value.
- Hands-on strategic consultancy services, loaned executives, or complete project teams.
- When you need it, for as long as you need it.
- Accountability: Payment linked to successful outcomes achieved against time, quality and cost based deliverables.
- Flexible commercial options including fixed price contracts

You benefit from expert business interventions that support at multiple levels:

- Strategic planning & decision making
- Management and execution of key business activities including drug development programmes, outsourcing, technology choices and investments.
- Cost optimisation programmes and strategic workforce optimisation.
- Optimised resourcing of demand including strategic demand management and planning at portfolio level through to tactical resource optimisation.

Sharing “lessons learned” from across life sciences and other industries to drive innovation that delivers competitive advantage.

- New development models drawing elements from open/collaborative innovation enterprises.
- Enhancing risk management practices by learning from mature industries.

HOW DO WE WORK WITH YOU?

We work as your trusted colleagues, accountable, aligned, committing quality and performance excellence, from advice on specific issues to full outsourcing:

Advice:

- Consulting advice on issues requiring rapid response
- Guidance on difficult to solve problems

Partial Outsourcing

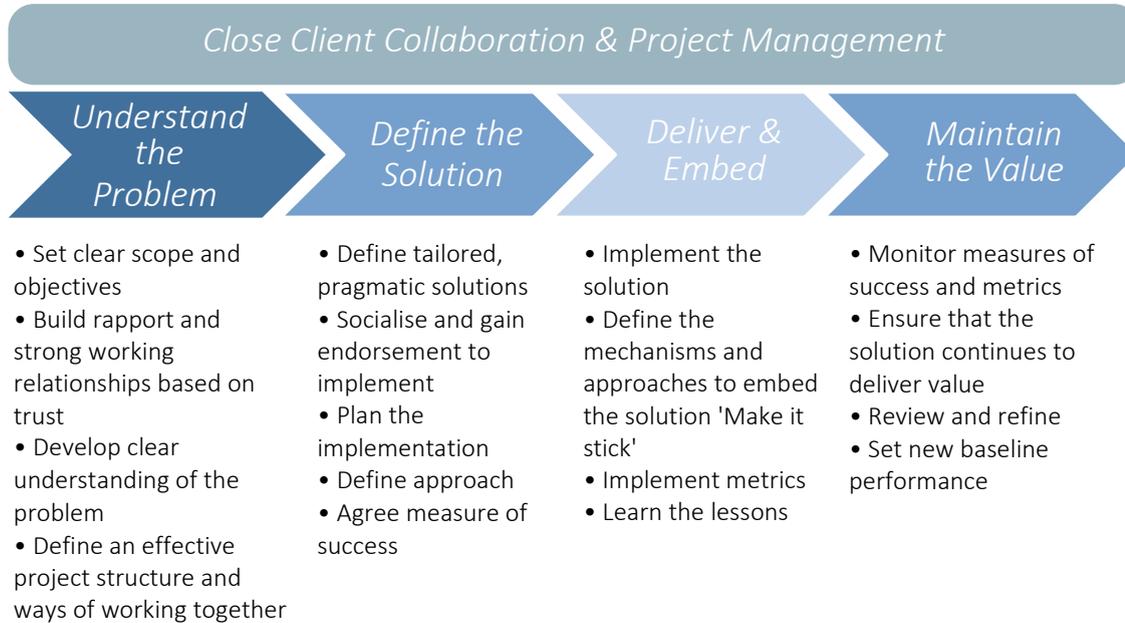
- Lead components of major projects
- Individual experts dedicated for extended periods

Full Outsourcing

- Fully loaned executives
- Turn-key projects with dedicated teams

HOW WILL WE OPERATE ON YOUR PROJECT?

We create tailored solutions and seamless integration to fit your product, your organisations' needs and your goals. These are not quick fixes but any changes are aimed to be embedded – it's a solution that lasts and not a quick sticking plaster.



CONTACT FOR FURTHER INFORMATION



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