An introduction to Volt Pharma Associates Commercialisation (VPAC) 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."

Volt Pharma Associates (VPA) – Overview

OUR ETHOS

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

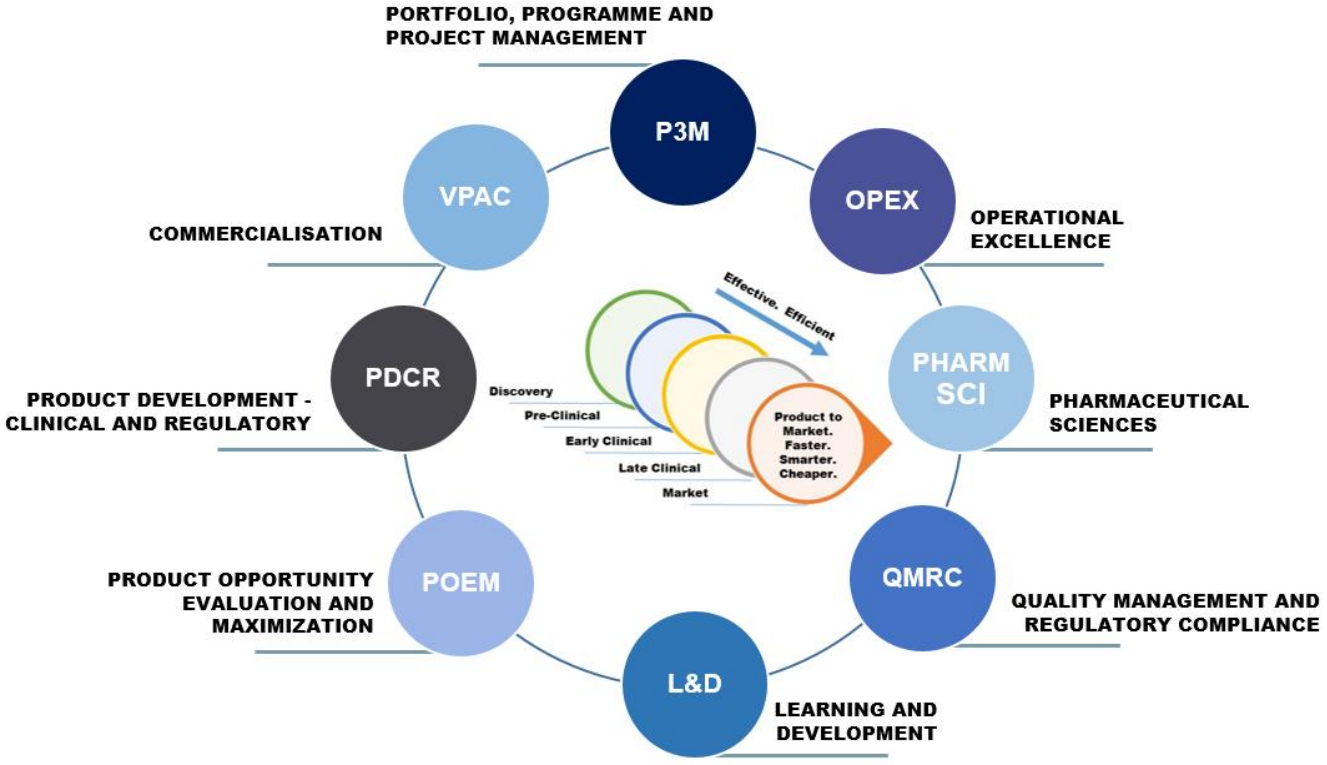
WHO WE ARE

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.

VPA is part of Volt Information Sciences, Inc., a global provider of talent, technology and consulting services. Volt is a highly successful, 6 Sigma company with offices in North and South America, Asia and Europe.

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 and organisations.



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 (VPAC) Services

SERVICES

Achieving a marketing approval is just one of the hurdles when defining the potential success of the development of a product. Volt Pharma Associates 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.

TEAM BIOGRAPHIES

Dr Richard Phillips MBBS MFPM MBA

Richard qualified in medicine at St Mary's Hospital Medical School, now Imperial College in London. After several posts in the NHS, he joined Pfizer as a medical advisor responsible for rheumatology and infection. After obtaining an MBA from Kingston Business School, he set up the Outcomes Research Group at Pfizer. In 1999, he founded the Goffin Consultancy to provide evidence-based health economics and data review for the healthcare industry. His clients have ranged from start-ups to blue chip pharmaceutical companies as well as OTC companies, medical device companies and private equity houses wanting to review potential investment opportunities.

He brings a wide background in clinical studies, economic analyses and meta-analyses following nearly 29 years in the pharmaceutical industry as well as wide experience in presenting clinical and health economic studies both in print, at symposia and for training purposes. He has worked with several companies in the health technology assessment, pricing and reimbursement and market access fields. He is the author of numerous market, data & literature reviews and core-value documents.

Nick Brindley MSc

Nick has worked in the pharmaceutical industry for 35 years and for Pfizer for 28 years. He has wide experience in a variety of roles from manufacturing and QC to European marketing, where he was responsible for the European launch of Viagra and later had responsibility for the European Urology and Ophthalmology businesses.

Nick also has more than 10 years of experience in commercial development roles. He has worked at all stages of product commercial development, from working with Research scientists on pre-development compounds and programmes through phase 2 and 3 progression to pre- launch, and across most therapy areas including oncology.

He was commercial site head on two Pfizer R&D sites. His latest role was as Head of New Product Commercialization for Europe. Nick has also been responsible for Licensing & Development projects across a number of therapy areas in his various roles including assessment of orphan drugs. Nick brings a wealth of commercial experience and expertise in the assessment of potential product value and designing development programmes to help achieve that value from both labelling and P&R consideration.

Ellen Sarewitz MA

An award-winning leader in the global healthcare arena with a first-class track record gained in the pharmaceutical, biotech and not-for-profit sectors, Ellen Sarewitz delivers integrated results-orientated services to a wide range of clients in both major and emerging markets.

Ellen combines authentic market insights and an empathetic approach with deep experience to deliver impactful strategies from early market development to product launch and lifecycle management, as well as helping clients establish a leadership profile in therapeutic areas, such as oncology, endocrinology, cardiovascular disease, immunology and acute medicine. She offers strong team management skills and expertise in brand planning, market shaping strategies, strategic communications and partnership planning, market access, and issues preparedness.

James Brown BSc (Hons)

James Brown has held senior management roles at several pharmaceutical companies including Pfizer, Novartis and Bayer Healthcare. He has over 25 years of commercial experience, encompassing a broad range of therapeutic areas and product launches with both medium-sized to world-leading brands. He is also experienced in early phase drug development as well as leading international development teams. He holds a Joint Honours Degree in Chemistry with Business Administration.

Significant multi- cultural experience having lived and worked in five countries and successfully led diverse matrix teams. Relishes new challenges and experiences. Exhibits strong interpersonal skills and people management expertise. Able to work effectively with all management levels with the ability to motivate teams to deliver high quality performance.

Graham Finch BSc BEng MSc

Graham is a consultant to biopharmaceutical organisations providing strategic and analytical guidance to Research and Development and Business Development investment decisions. He has a background in product and portfolio strategy, commercial analysis and valuation, business development, due diligence and deal terms for licensing and acquisition, market and customer analysis, investment and risk analysis.

Graham has eleven years' experience working for a major pharmaceutical company and recent independent experience providing consultancy to biotech and mid-sized pharmaceutical organisations. He is a Graduate of Physics and Engineering with an MSc in Operational Research from the London School of Economics.

CASE STUDIES

The following examples by phase illustrate the experience and value that VPA Commercialisation team 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 rand 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 VOLT PHARMA ASSOCIATES 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

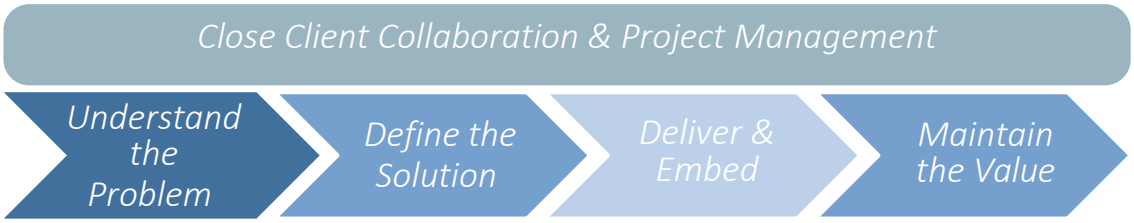
- Lead components of major projects
- Individual experts dedicated for extended periods

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.



- Set clear scope and objectives
- Build rapport and strong working relationships based on trust
- Develop clear understanding of the problem
- Define an effective project structure and ways of working together

- Define tailored, pragmatic solutions
- Socialise and gain endorsement to implement
- Plan the implementation
- Define change management approach
- Agree measure of success

- Implement the solution
- Define the mechanisms and approaches to embed the change 'Make it stick'
- Implement metrics
- Learn the lessons

- Monitor measures of success and metrics
- Ensure that changes continue to deliver value
- Review and refine
- Set new baseline performance

CONTACT FOR FURTHER INFORMATION

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