VOLT®

An introduction to Volt Pharma Associates Product Opportunity Evaluation and Maximisation (POEM) Services

"When research begins to show promise, it's time to determine the best investment strategy and the optimum development path to market. This is what we do."

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.

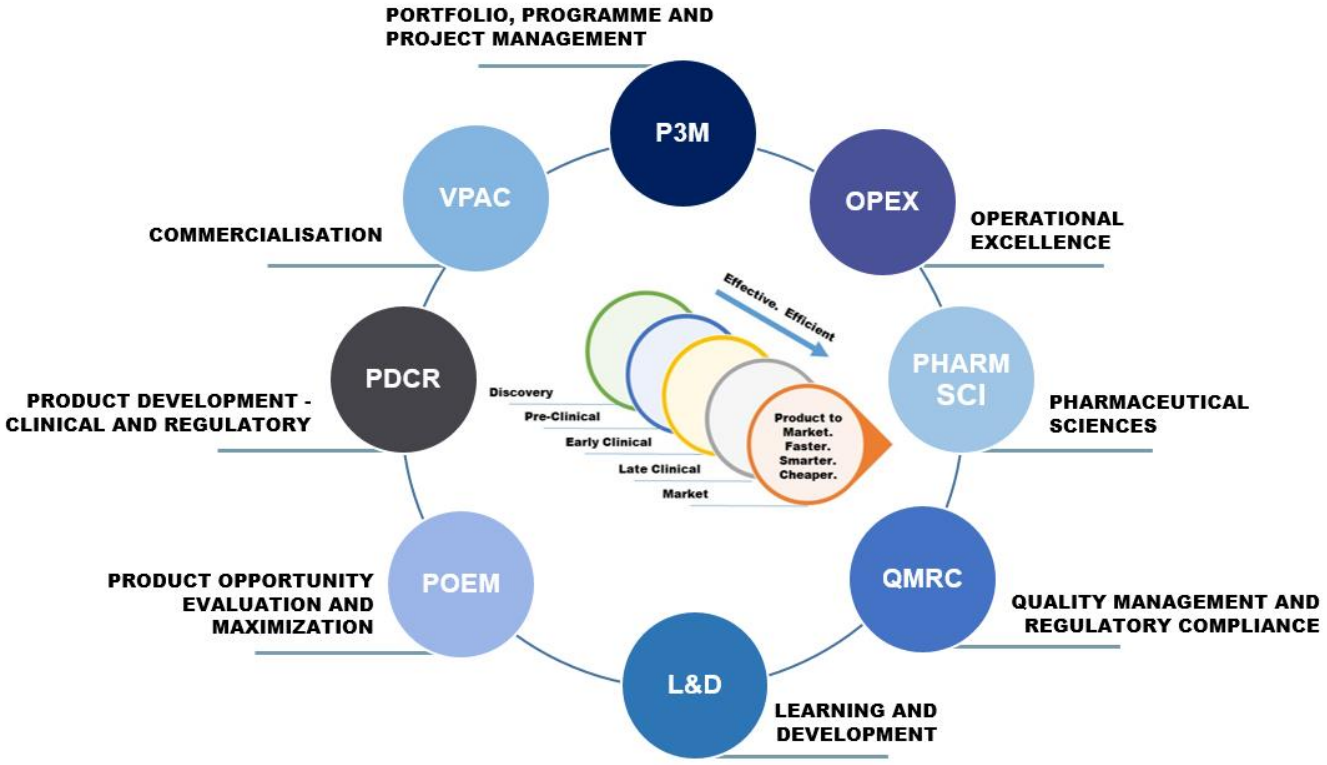
WHO WE ARE

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.

Product Opportunity Evaluation and Maximisation (POEM) Services

For assets in the preclinical to Phase 2 space evaluating the opportunity and planning the best development path to patient and market becomes a priority. The POEM group can help to maximise the value of assets by providing an integrated view of the therapeutic area landscape, the competition, the development options and challenges, the regulatory path, and commercial considerations and risks.

Additionally, for those looking to acquire or licence assets we can provide Due Diligence services with full valuation, deal terms, and legal and IP guidance.

SERVICES

1. Overview – our main focus:

   - Evaluation of opportunity landscape, for:
     - Investors looking for deals and partnerships
     - Owners with early stage assets under development
     - Owners looking to attract funding.
   - Assessment and development planning of assets:
     - Integrated Product Development services
     - Target product profile planning, including disease area and patient population selection
     - Path to market planning for assets in Pre-clinical to Phase 2b phases
     - Commercial viability and valuation for early stage assets
     - Business case development for early stage assets to attract funding
   - Due Diligence services
     - Asset Due Diligence
     - Data Due Diligence
     - Independent guidance on asset health

2. Specific services we are experts in:

   - Commercial assessment and valuation of biopharmaceutical assets
   - Product development strategy, planning and execution
   - Therapeutic area & competitor intelligence
   - Legal compliance audit of research data
   - Financial analysis and deal terms for licensing and acquisition

3. Clients - we help clients by tailoring industry best practice to individual needs:

   - Investment groups looking for opportunities:
     - Scientific/technical, clinical, commercial, legal, patent, regulatory and financial advice
     - Early stage asset evaluation and optimisation for disease area, target product profile and path to patient/market
     - Early stage commercial evaluation
     - Selection of opportunities across disease areas, mechanisms and technologies
     - Custom built portfolio with appraisal of risk, timing of exits and likely value
     - Asset exit (sale) strategy
     - Full or partial Due Diligence service to support acquisitions and licensing

- **Academic spinouts, start-ups, owners of IP:**
  - Building of business case for asset/technology/IP/operational integrity to attract investment
  - Specific input to business case, e.g. market potential, pricing, legal, commercial transparency, exit strategy, financial issues
  - Targeting and approaching of funding groups.

- **Groups owning assets under development:**
  - Expert advice for specific questions
  - Monitoring of existing assets and portfolios to sharpen investment
  - Unbiased "reality check" on attractiveness of continued asset development
  - "Clean teams" for large Pharma groups with internal data confidentiality issues.

TEAM BIOGRAPHIES

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.

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.

Paul Fletcher MSc, PhD, MRSC, CChem

Paul is a Pharmaceutical professional with Business Development and Licensing experience covering a range of therapeutic areas. He most recently specialized in the field of Respiratory, Inflammation and autoimmunity.

After 29 years with "Big Pharma", Paul has a good understanding of the industry and of the entire partnering process from opportunity identification, through asset evaluation

and Due Diligence to negotiation and closing the deal. Across this process he has led teams comprising scientists, clinicians, finance professionals and lawyers.

Paul's experience of deal shapes, spans licensing, collaboration and acquisition and covers both inbound and outbound projects. He has worked on pre-clinical and clinical stage opportunities (development and marketed) and on both ethical (prescription) and OTC (consumer) medicines, with counter-parties from the biotechnology, "Big Pharma" and medical device communities. One of the transactions that Paul led was the 2010 Scrip Awards Licensing Deal of the Year.

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.

Mauro Placchi Dott. Chimica, MSc

Mauro is a clinical development consultant with 25 years' experience in early to late phase development with major pharmaceutical companies and contract research organisations including Pfizer, Merck Serono, European Organisation for Research and Treatment of Cancer and Quintiles. He developed clinical studies in more than 20 indications in various therapeutic areas including multiple sclerosis, psychiatry, oncology, dermatology and infectious diseases. He is detail-oriented, dedicated and skilled in all aspects of Phase 1 to 4 clinical trials including planning, organising, implementing, leading, controlling and reporting.

He led international teams of up to 40 for more than 50 projects and achieved primary results for 6 Phase 2 and 6 global Phase 3 pivotal studies. He delivered complex clinical projects performed in Europe, Russia, Africa, India, Australia, North and South America with GCP/International Committee on Harmonisation standards. He worked across multiple technology platforms, including small molecules, therapeutic proteins, monoclonal antibodies and devices and in differently targeted environments, including prescription drugs and consumer products.

Gaia Paolini Dott. Fisica 9MSc), MBCS.

Gaia has ten years of pharmaceutical industry experience. Her career covers twenty-five years in academia and industry, including IBM and Pfizer, combining scientific research, business analysis and data analytics. Her interests focus on aligning data and systems to business strategy by profiling, integrating and analysing scientific information. Her expertise spans knowledge discovery, process improvement and pharmaceutical data from chemical structures to clinical trials.

Examples of her work are automated information extraction algorithms for cell toxicity

and clinical safety data, the design of confidence scores for fast outlier detection and assessment of biological screening results, a data integrity control process for a chemical data warehouse and the development of multi-objective metrics to streamline ranking and selection of drug candidates. At Pfizer, Gaia won a Global Achievement Award and a Publication Award for her role in setting up an innovative knowledge base and data analytics system. Gaia graduated with a first class Laurea di dottore in Physics from the University of Rome and is a Member of BCS, The Chartered Institute for IT. She has publications in the fields of chemogenomics, applied mathematics, materials science and statistical physics.

CASE STUDIES

The following examples illustrate the experience and value that VPA POEM can bring to its clients:

Case study 1:

- *Situation:* A new therapeutic about to enter the clinic with a range of possible different indications and disease populations centred around progressive liver fibrosis and NASH. How to determine the best development path and target product profile, as well as explore the risk/reward balance between the various development options and pricing implications.
- *Service:* Built and executed a clear process to brainstorm and prioritize disease populations, identify key decision criteria, and test the sensitivity of those disease population options to the decision criteria. Then hybridized the most preferred populations to test the risk/return trade-offs
- *Result:* A clear development path with an early proof of concept in a niche population that built confidence so that an acceptable risk/return ration was achieved in a broader disease population

Case study 2:

- *Situation:* A big pharma client was looking to in-licence a compound in development in phase 3. They needed clarity concerning the value of the asset, how the remaining risk to market would be resolved, and how to structure and size the deal terms in terms of up-front payments, milestones and royalties.
- *Services:* A valuation, risk & financial analysis, benchmarked against current big-pharma licensing deals, provided a deal term structure and negotiation strategy.
- *Result:* Client was provided with a clear path forward in the negotiation.

Cast study 3:

- *Situation:* A not for profit group was looking to understand how they should make project selection decisions for projects entering into the clinical phase, and how the priority of these incoming projects could be seen against those already in the portfolio
- *Services:* VPA worked with the client to understand what critical aspects of a project were valued by the organisation and stakeholders. These were used to form the basis of a small number of criteria against which incoming, and existing, projects were judged. A model was developed that could not only score these projects against these criteria, but which could also explore project ranking sensitivities, "what if" analyses, and critical strengths and weaknesses on a common framework.
- *Result:* The client obtained a clear understanding of project value and was able to align all stakeholders around this. Incoming and existing projects were able to be compared, selected and prioritized using a common language, and buy-in for funding obtained

Case study 4:

- *Situation:* Licensing opportunity for a mid-sized pharma group.
- *Service:* A comprehensive market and competitor assessment, revenue projections and commercial cost assessment, and an asset valuation before and after deal terms and royalty payments to third parties.
- *Result:* Client had an objective view of the opportunity and risks associated, which led to a clear go forward decision.

Case study 5:

- *Situation:* Private equity house considering investment in a small pharmaceutical company in Parkinson's disease area.
- *Service:* An assessment of the competitor and therapeutic environment and regulatory position of the product, and a review of the clinical data, revealed that the target company had a range of products that had been acquired over several years but were of little future value.
- *Result:* As a result of the review, the equity company decided not to invest.

Case study 6:

- *Situation:* A specialty pharma start-up needed to determine the optimal target patient group, plan a path to market, and develop a valuation for each asset.
- *Service:* Disease area strategy and exit strategy for assets, commercial due diligence and valuation, competitor and customer analysis for an exit strategy, and a return on investment analysis.
- *Result:* Clear view on the financial opportunity and enabled a robust business plan and investment case for attracting Venture Capital funding.

Client testimonial:

"…The VPA team supported our Due Diligence in a highly professional manner with a great expertise. The team was quick and always available for discussions and alignments throughout the process and they provided an excellent analysis. Working with VPA was a great pleasure…"

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

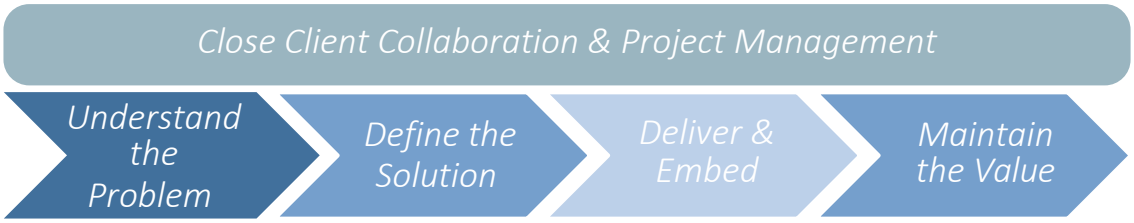
- Lead components of major projects
- Individual experts dedicated for extended periods

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.



Understand the Problem	Define the Solution	Deliver & Embed	Maintain the Value
• 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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