Can a small service provider offer high-quality advice?

How a small team of experienced professionals can resolve issues instead of creating new ones

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* “We are not just consultants. We achieve and maintain MAs on behalf of our clients.”

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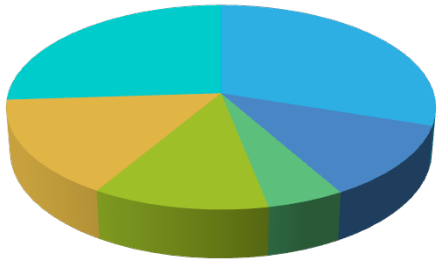
Services offered to the Pharma Industry since 2009



- MAA filing
- PIP advice
- Orphan designation
- Scientific advice
- Safety review
- Market Access
- Audits

Since 2009 PhD has provided assistance to pharmaceutical companies in Europe.
Our personal 'hands-on' approach sets us apart from our competitors. This includes senior involvement in all stages of a project and a personally managed network of consultants. Combined with a flexible approach and a can-do attitude, this allows us to gain the deepest insights to in turn provide actionable and highly targeted recommendations to our clients as well as representing them at key meetings with Regulatory Authorities.
The company has also dealt with a number of MHRA inspections for PV and GCP providing audits and inspection readiness training.

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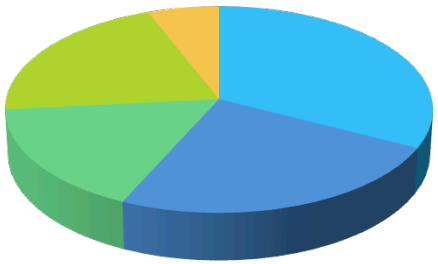
Quality, Compliance and Audits



Since 2009 we have provided Auditing of PV systems, processes and documents in Europe and Asia/Pacific. Our audits include marketing partners, affiliate/local company, clinical sites, CROs or other service providers. We have assisted with quality review of medical and regulatory documents and full document audit.

More than this, we have assisted large clients in developing risk-based audit matrix systems, gap analysis and due diligence. Our experience includes working with small and large molecules including vaccines and other biologicals.

We provide due diligence process checks and regulatory compliance reports. We offer audits on an as-needed basis to our major clients.

Since 2009 Pharma Design has been engaged with Academia and Universities providing training on Quality Management Systems.

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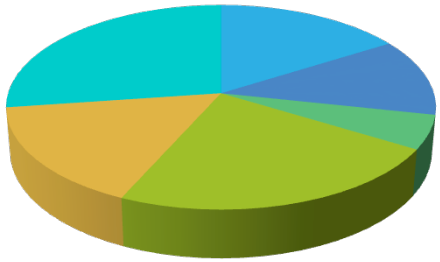
Services offered to International Organisations since 2009



- Regulatory differences across countries
- HIV & AR analysis in 3rd World countries
- Patenting issues
- Patient access to medicines
- Special populations requirements
- Disease burden analysis in poor countries

Since 2009 PhD has provided advice and analysis to International Organisations.
We have produced a number of study reports on Regulatory and Patient access issues in 3rd World countries as well as data on disease burden in specific areas.

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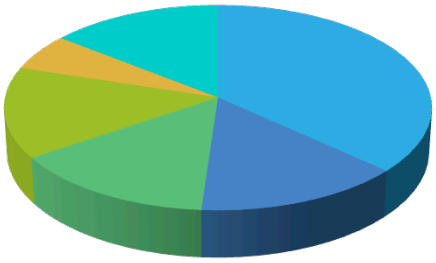
Regulatory Filings



- CAPs
- MRP/DCP
- Variations
- Scientific advice
- Referrals
- CTAs

From early development to market launch and post-marketing license management, we have supported companies with a comprehensive and efficient service including all activities related to the life-cycle of medicinal products.

We try to explore the aspects of strategy design according to the product's intrinsic value, the benefit/risk profile, the various regulatory requirements and market conditions to allow our customers make the right decision at any stage of the product life-cycle.

Assisting in the decision making process is combined with ongoing 'maintenance activities' that are required at any stage to ensure compliance. These include mainly variations and communication with Competent Authorities.

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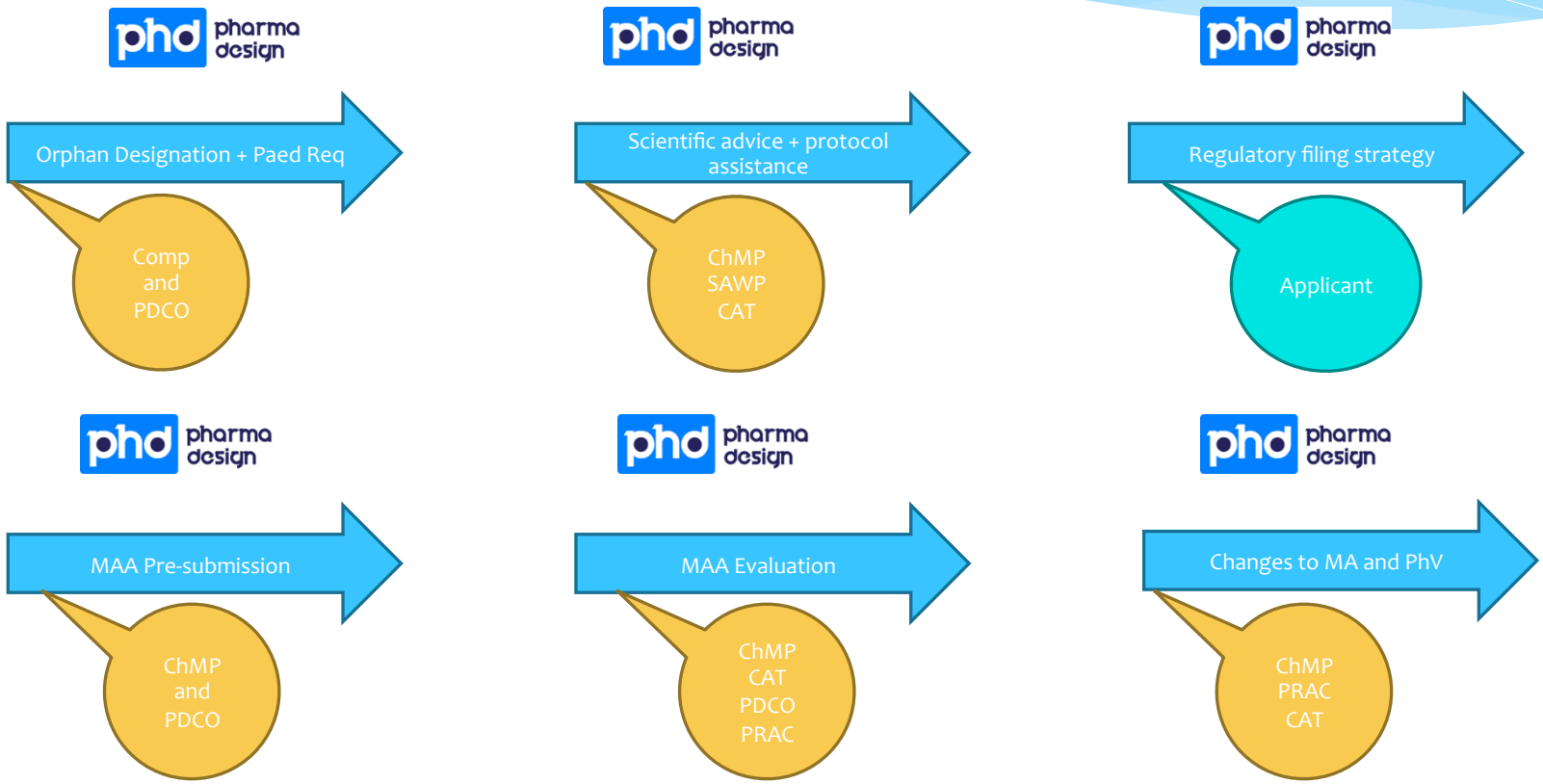
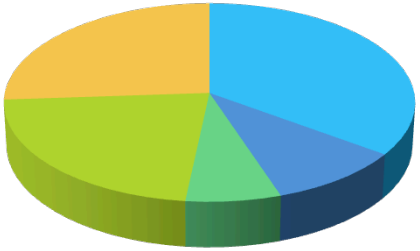
Involvement of PhD in EMA Committee meetings during drug development



Market Access



PHD has a highly experienced Market Access team, with a proven track record of success in health outcomes research, value-based pricing, scenario planning and pricing agency/ authority interactions.
PhD has provide support during early phase RCTs through Value Hypothesis Formulation and, at later stages, through hypothesis verification and optimisation.
Our understanding of payer priorities informs our development of value dossiers. We have developed full global dossiers across a variety of disease areas including auto-inflammatory disorders, oncology and urology. We implement an internal quality control system that combines use of experienced medical writers, edited by experienced market access consultants with medical backgrounds, health economists with 15 years' experience and a Consultant Pharmaceutical Physician to check all content from a medical affairs perspective. Our team of consultants have strong understanding of pricing and market access issues in key markets including US, EU5 and other important EU markets.

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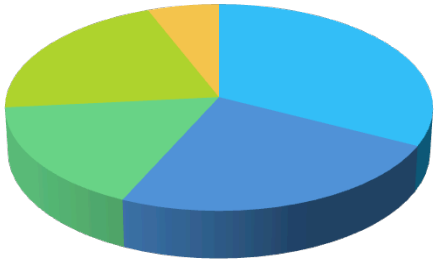
Safety



Since 2009 we have provided high quality Safety documents to major pharmaceutical companies, including clinical and post-marketing. We have assisted with safety review of clinical results for Marketing Applications and responded or assisted our clients in answering questions raised by Regulatory Authorities. We have also assisted companies with products under additional monitoring, gathered and compiled safety data on black triangle and special surveillance products in the UK.

We specialise in producing safety documents according to the new GVP legislation. From this point of view we have being recently translating old periodic safety reports into GVP format, while performing a review of the Risk/Benefit profile as required from the new legislation and aligning all Company safety documents for consistency.

We have produced Pharmacovigilance System Master Files on behalf of our clients.

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The Team

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