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*Science may set limits to
knowledge,
but should not set limits to
imagination.*

- Bertrand Russell



WHO WE ARE

Pharmalys is a Contract Research Organisation (CRO) based near London in the United Kingdom.

With more than 30 years of combined experience in clinical operations within the pharmaceutical industry, at Pharmalys we have extensive expertise in managing clinical trials across a wide range of therapeutic areas.

Our professionals have previously worked in small, medium and large pharmaceutical companies, in full service CROs and at investigational sites. This gives us a very good understanding of the industry and allows us to develop a unique approach to meet our clients' targets.

WHAT WE DO

We provide the pharmaceutical and biopharmaceutical industries with tailor-made clinical trial services. We can either fully manage local or international trials or provide individual services to complement our clients' in-house competencies.

At Pharmalys, we constantly scan the horizon for innovation and cost-effective customer-focused solutions.

We are committed to the highest professional standards and aim to fulfill our mission and earn our customers' trust by providing an outstanding quality of service.

OUR CORE COMPETENCIES

We offer a wide range of services covering all clinical trial phases from trial feasibility right through to study reporting.

Feasibility Assessment & Site Identification:

- Search from our database of qualified investigators
- Fast and realistic results on trial feasibility
- Assessment of:
 - Each investigator and site team competencies and experience
 - Availability and workload
 - Site facilities
 - Recruitment potential

Project Management:

- Upfront planning and preparation of a clinical trial road map
- Project team set up
- Global coordination of teams
- Ongoing anticipation of risks
- Proactive preparation of back-up scenarios & implementation of corrective actions
- Ongoing tracking of key milestones and budget
- Reporting

Regulatory Submission:

- Preparation of the submission dossier
- Attendance of Ethics Committees meetings together with the Chief Investigator
- Liaison with the competent authorities
- Support given to investigational sites for their local submissions
- Communication of approvals to your project team in a timely manner
- Periodic reporting required by Ethics Committees and competent authorities

Clinical Monitoring:

- Investigational site identification and qualification
- Collection, review and tracking of essential documents
- Site initiation, ongoing monitoring and closure
- Reporting and tracking of monitoring activities
- In-house site management

Quality Assurance:

- Investigational site facilities
- Trial data
- Trial master files and investigator site files
- Monitoring compliance
- Clinical trial documents including the clinical trial report
- Quality process implementation and improvement

Biometrics:

- CRF design and review
- Data management plan
- Database design and validation
- Data entry, data clarification & coding
- Sample size and power calculations
- Randomisation
- Statistical analysis

Medical Writing:

- Protocols
- Investigator Brochures
- Paediatric Investigational Plans
- Patient Information Sheets and Informed Consent Forms
- Trial reports

Consulting:

- Scientific, regulatory, operational and business consulting for:
- Programme/trial planning and conduct
 - Process design and improvement
 - Resource planning and management
 - Vendor selection and management