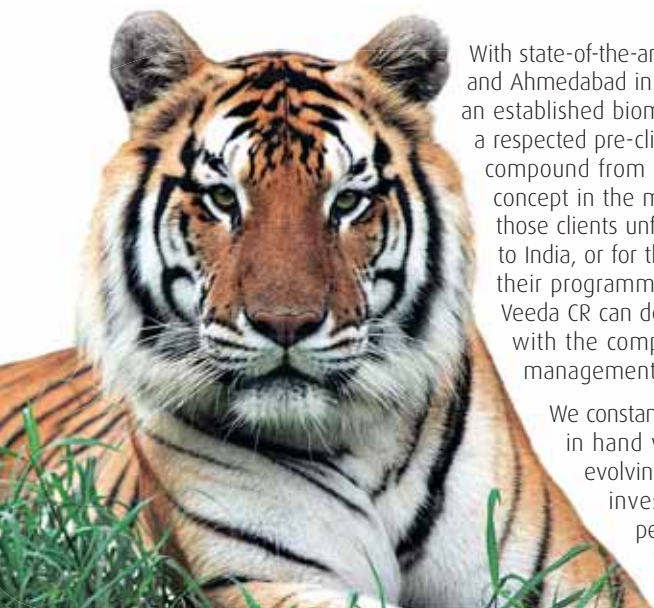


quality research solutions



Veeda Clinical Research is a vibrant Anglo/India CRO which brings together 20 years of clinical research expertise with the intellectual ability and tireless work ethic of the East. From First-in-Man studies to large scale Bioequivalence/Bioavailability comparator studies Veeda Clinical Research offers a fully integrated package to meet your early clinical development needs.



With state-of-the-art phase I facilities in Plymouth in the UK and Ahmedabad in India, fully accredited GLP laboratories, an established biometrics team in Belgium and India and a respected pre-clinical partner, Veeda CR can take your compound from pre-clinical development to proof of concept in the most timely, cost effective manner. For those clients unfamiliar with the benefits of outsourcing to India, or for those who choose to strategically spread their programmes of work between two continents, Veeda CR can deliver significant cost savings combined with the complete reassurance of a UK project management service.

We constantly strive to look forward, working hand in hand with our clients, responding to their evolving needs, anticipating regulatory change investing in both our facilities and our people, seeking to assert our position at the forefront of clinical research.





Clinical Facilities

- UK phase I unit - 61 bed capacity with 21 monitored beds
- India phase I unit - 116 bed capacity with 12 monitored beds
- Telemetry (full disclosure)
- Mac 5000 ECG machines, GE wall-mounted monitors
- Capability to store ECG data in FDA format via a GE Muse System
- GMP accredited pharmacy and drug preparation area with a laminar flow cabinet, air conditioning and centrally monitored/alarmed drug storage facilities
- In-house catering allowing the Unit to provide for specific dietary requirements
- QP services
- On and off-site archive facilities

Clinical Experience

- First-into-Man
- Pharmacokinetic/Pharmacodynamic
- Fast through-put Bioavailability/Bioequivalence/Food Effect
- Drug Interaction
- QTc studies
- Proof of Concept
- Long residence studies

Areas of Expertise

- Cardiovascular
- Respiratory
- CNS
- Immunology
- Infectious disease
- Anaesthetics
- Gastro-Intestinal
- Women's health
- Elderly studies
- Diabetology including Glucose Clamping
- Renal disease
- Oncology
- Dermatology





Volunteer/Patient Recruitment

Volunteer recruitment is handled by dedicated recruitment teams. As well as the standard populations of volunteers for studies such as fit young men, Veeda CR has a reputation for attracting more difficult to recruit populations, with an excellent record in the UK for recruiting:

- Healthy males and females
- Female populations including non-sterilised, sterilised and post-menopausal
- Asthmatics
- Hypertensives
- BPH patients
- Diabetics

In India, Veeda CR has access to vast patient populations and has specific expertise in recruiting patients with:

- Cardiovascular disease
- Oncology
- Diabetes
- Renal disease

For specialist populations and patients both our recruitment teams in the UK and India are experienced at liaising with our local GPs/Physicians and have well established relationships with regional hospitals.

Quality Assurance and Project Management

Strong quality assurance permeates the culture, service and operating philosophy of Veeda CR. Veeda CR operates a global Quality, Training and Project Management system to ensure synergy across sites. It continuously reviews SOPs and working practices to identify areas that can be developed to improve service and client quality audits are actively encouraged and facilitated.

Each study has an experienced project manager

working with a dedicated clinical team who take the trial from inception to completion. This approach delivers good direct communication through a single point client interface, clear lines of accountability and high levels of consistency and continuity throughout the study.

Veeda CR offers a gateway to India for clients new to the sub-continent and offers UK project management to help facilitate this transition.



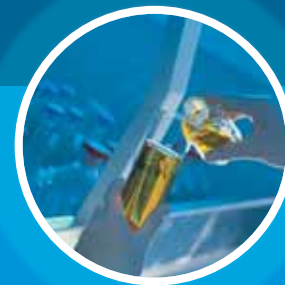
Regulatory Services

Veeda CR has dedicated resources which enable us to provide regulatory solutions to support our clients' product development programs. We can also provide on-going regulatory support once your product is registered.

Our broad functional and therapeutic area expertise enables us to provide specialised inputs to clients according to their needs. We have substantial experience in Europe and the US.

- Regulatory Strategy input to the Product Development Plan
- Preparation of Clinical Trial & Ethics Committee applications and on-going support for trials including Safety Reporting
- Preparation of Product Registration applications, Drug Masterfiles and Post-approval regulatory submissions (renewals, variations, defence documentation).
- Project management and co-ordination of registration applications including interfacing with Regulatory Authorities on behalf of clients
- Provision of Clinical, Quality and Safety (CQS) Expert Reports and Summaries
- Manufacturing Change Control
- Training programmes for the EU Clinical Trials Directive





Pre-clinical Services

Veeda CR's strategic partnership with Advinus provides the opportunity to offer a complete range of services from basic chemistry, formulation, toxicology and bench pharmacology. The value of this relationship lies in our ability to support the chain of operations needed for drug development especially for the smaller clientele who may need a diversity of services. Advinus operations are organised into two separate businesses centred around Discovery and Development respectively.

Based in Bangalore, India, with a top-level management team with backgrounds in major Western pharma, Advinus' Development business provides services to pharmaceutical, biotech and agro companies for global registration of pharma and agrochemicals. By focusing on R&D services Advinus is able to ensure that there is no dilution of the scientific and managerial focus because of downstream functions including manufacture, marketing and commercialisation of API and finished formulations. Advinus offers an integrated platform for preclinical and early clinical drug development based on expertise in:

- Custom Synthesis
- Process Chemistry and Research
- Formulation Development
- Analytical R&D
- Stability Testing
- DMPK/Clinical Pharmacology
- Safety Assessment

Advinus is promoted by the Tata group, one of India's largest and most respected business houses providing a well resourced facility and financial stability going forward.





a proven track record

Veeda CR has laboratory services at both of our clinical sites in Plymouth, UK, and Ahmedabad, India. All of our services are designed to support studies conducted internally in our clinics, as well as being true stand-alone services for external studies, whether pre-clinical, or single/multi - site clinical studies.

Veeda CR's laboratories in the UK are GLP accredited and offer a comprehensive range of laboratory services, from basic laboratory safety analyses to more complex testing regimes requiring specialist techniques. The UK laboratory has a proven track record for ligand binding pharmacokinetic analysis, Immunogenicity (Antibody monitoring), and the analysis of Biomarkers.

Veeda CR's laboratories in India provide bioanalytical services for the analysis of drugs and metabolites for small molecules. The laboratory is equipped with triple-quadrupole LC/MS/MS systems and High-throughput HPLC systems. These are supported by Tomtec Quadra 96 robotics allowing automation of extractions and analysis on 96-well microplates. The whole service is underpinned using WATSON LIMS®.





Our Group Laboratory Services cover:

- Clinical pathology laboratories for safety analysis
- Bioanalysis of drug and metabolites for PK analysis - Small and Large molecules
- Immunogenicity testing
- Specialist and bespoke Biomarker services - safety, efficacy, and pharmacodynamic using a wide range of analytical techniques and platforms.

Services Offered

- Routine Safety Assessment i.e. Clinical Biochemistry, Haematology
- Method development
- Establishment of immunoassays in biological matrices from different species
- Validation of immunoassay techniques to FDA guidelines in accordance with GLP/GCP regulations
- Bioanalysis for parent drug and metabolite concentrations in samples generated from preclinical and clinical studies for Toxicokinetic and Pharmacokinetic assessment
- Measurement of Biomarkers for Research, Drug Development, Pharmacodynamics and Safety assessment
- Monitoring of antibody response (immunogenicity)
- Validation of methods to FDA guidelines in accordance with GLP/GCP regulations

Techniques Currently Offered

Veeda CR has a range of state-of-the-art, fully automated analysers, providing rapid, precise and accurate results.

- Enzyme based immunoassays i.e. ELISA and EIA
- Chemiluminescent based Immunoassays (CLIA)
- Fluorescent based immunoassays i.e. FIA, FPIA and DELFIA
- Radioactive based immunoassays i.e. RIA, IRMA and RIPA
- Multiplexed Assays
- Flow Cytometry, Cell Based Assays
- Hybridisation Assays
- Laser Nephelometry, Turbidometric Assays, Coagulation Assays



unleashing the
power of India



Veeda CR's Biometrics unit has divisions in both Europe and in India and specialises in providing high quality data management, statistics and report writing in accordance with global regulatory standards.

Veeda CR Biometrics combines 18 years experience in all phases of clinical research, in an extensive range of study types, with the high capacity and cost effectiveness of the Indian subcontinent.

The Veeda CR data management and biometrics group offers:

- Protocol design & review
- Randomisation
- Case Report Form (CRF) design, review and production (paper & EDC)
- Database design
- Data entry
- Data validation/verification
- Medical review
- Medical term coding
- Quality management procedures
- Data manipulation (including conversion to CDISC structure)
- Statistical analysis
- Medical writing

The European data management and biometrics group is involved at an early stage in all early phase studies conducted in the clinical facilities of Veeda Clinical Research, thus ensuring that the sponsor receives accurate data in the required format and allowing a statistically founded conclusion on the study hypotheses.

The broad experience of the European group, in all stages of development and in all therapeutic areas, is an added value in early phase studies. This ensures, at this early stage in drug development that the requirements which will be encountered in later stages of development are taken into account and that standardisation of data management and analysis procedures can be ensured throughout the clinical development phases.





high quality
data management





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