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Regulatory Science

Consultancy

Services in Study Management

When toxicology studies need to be commissioned RSA is ideally qualified to provide study management and monitoring services. Our team of experts can design, monitor, report and interpret regulatory guideline and investigative toxicology studies whether for standard regulatory submissions or more open-ended research investigations. RSA can manage studies on your behalf, reviewing the resulting data and draft reports, preparing appropriate summaries and regulatory documents and provide advice on classification and risk assessments. The RSA team includes consultants with specific expertise in carcinogenicity, reproductive toxicology, genetic toxicology, neurotoxicology, endocrine disruption, pathology, metabolism and kinetics, operator exposure, safety pharmacology and regulatory affairs. **We have an outstanding track record of dealing with a wide range of companies drawn from many different industrial sectors, government agencies and regulatory bodies.**

We offer:

- Advice on study /programme design, CRO selection and testing strategy
- Placement and Contract Negotiation
- Guidance on regulatory acceptability and dose level selection
- Protocol review
- Day to day study management and monitoring on behalf of the sponsor
- Problem solving and data interpretation
- Site visits
- Project management to ensure delivery to time
- Proactive communication with sponsor and CRO
- Review of study reports
- Preparation of report, summary or other data submissions to meet relevant legislation (e.g. REACH)
- Study Data Interpretation

For more information

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