



Cardiovascular/Metabolism Therapeutic Area Practice



4,500

PAREXEL has managed cardiovascular/metabolism trials
of every size, from one to 4,500 sites

PAREXEL

Meeting a worldwide challenge

Cardiovascular disease claims millions of lives every year around the world—more than the next three leading causes of death combined, according to the American Heart Association. Diabetes and other metabolic diseases are widespread too, affecting millions in the United States alone.

Although the demand for treatments is urgent, companies must overcome several hurdles to bring products to market. Cardiovascular mortality trials may require thousands of sites and tens of thousands of patients. There are also complexities in endpoint identification, reporting and adjudication. These factors can delay approvals and increase costs.

The PAREXEL Cardiovascular Therapeutic Area Practice can help you meet these challenges with well planned, efficiently managed and on-time trials worldwide. We provide you with best-practice management across the entire therapeutic area, including drug development, regulatory consulting, Phase I-IV trials, and post-marketing commitment studies.

A leading biopharmaceutical service company, PAREXEL is ready to partner with you to develop your product with the highest quality, safety and compliance.

We keep your international studies on schedule

More than other therapeutic areas, cardiovascular/metabolism compounds or devices require extremely large, international studies in order to reach results with statistical significance.

With monitoring experience in over 60 countries and a database of 9,000

investigators worldwide, PAREXEL can keep even your largest studies on track. In the last few years, we have conducted many cardiovascular/metabolism studies involving 2,000 or more sites on multiple continents.

We also maintain relationships with leading academic research centers, often working with them to manage large-scale trials

Naturally, we have the resources to keep your Phase I-II trials on track and in budget. We offer individually tailored cardiovascular programs through our clinical pharmacology network of over 600 beds worldwide in Berlin, London, Bloemfontein, George and Port Elizabeth, South Africa; Los Angeles/San Diego and Baltimore, USA.

Clinical expertise leads to better trial planning and management

PAREXEL offers in-depth clinical expertise to guide your trials at every stage. Our staff includes over 100 physicians with specific cardiovascular and metabolism experience, and our project managers have an average of 11 years of experience in clinical research.

Chances are we have managed a study similar to yours. In the past five years, we have conducted nearly 400 trials for indications such as Acute Coronary Syndromes and Coronary Artery Disease, PAD/Thrombosis, Pulmonary

The Virtual Panel System, PAREXEL's unique technology, allows medical experts from around the world to consult and adjudicate on endpoint decisions.



Hypertension, Venous Disease, Arrhythmia, Diabetes, Arterial Hypertension, Dyslipidemia/Obesity, Heart Failure and many others.

This experience is especially important in cardiovascular and metabolism studies. By understanding the underlying mechanisms and the complex nature of the disease, our cardiologists and endocrinologists can provide advice on study design, help select the right sites and subjects, and navigate the variety of regulatory issues. Many clients use our deep expertise to help train their personnel and their investigators in the cardiovascular or metabolism indications, the clinical trial strategy and implementation, as well as standards of care around the world.

Innovative technology sets your studies apart

A major challenge in cardiovascular and metabolism trials is centrally assessing and adjudicating clinical end-points, with specific difficulties when determining the cause of mortality. There are often X-rays, scans or other images that need to be

centrally managed and adjudicated by independent experts. To meet this demand, PAREXEL has assembled one of the finest medical imaging groups in the world, through Perceptive Informatics, our technology division. Our radiologists and medical specialists ensure that your image acquisition is standardized across all sites.

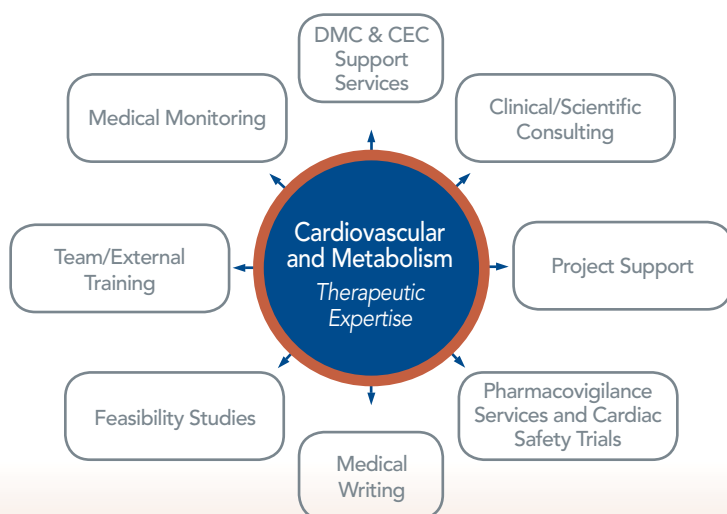
In addition, PAREXEL leads the industry in eClinical technologies that allow cardiovascular and metabolism specialists from around the world to participate in blind adjudication panels via the internet, sharing images, consulting with colleagues, and rendering decisions. Known as the “Virtual Panel System” for endpoint management, this system provides automatic tracking of each event and related images and documents.

Furthermore, your trials are managed throughout with the help of our industry-leading technology that enables us to streamline the overall planning, management and reporting of trials, which reduces costs and accelerates results.

PAREXEL's Cardiovascular/ Metabolism services include:

- Full clinical services for Phases I – IV
- Proven experience in mega-trials and endpoint trials (e.g., MACE, CV mortality)
- Planning and study design
- Feasibility studies to quantify how, when and where
- Site selection including identification, evaluation, selection and recruitment
- Trial management
- Analysis, reporting and NDA submission
- Special ability to understand and navigate regulatory issues
- Post trial studies and marketing

Integrating Medical Expertise in Cardiovascular and Metabolism



PAREXEL's Cardiovascular/Metabolism Therapeutic Area Team has the expertise to help with every facet of your drug development efforts.

Companies large and small rely on PAREXEL

We have worked with hundreds of companies that rely on our strong knowledge in product development and regulatory strategies, through design and conduct of clinical studies, to approvals and marketing. PAREXEL's

deep, focused expertise and extensive experience in cardiovascular/metabolism can help improve your chances of success and get your product to the next milestone and to the patients who need it.

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