Vitalograph Cardio-Respiratory Clinical Trials Services

Vitalograph specialize in delivering standardized equipment and centralized cardio-respiratory data capture services and patient reported outcomes for clinical trials.

When you choose Vitalograph as your clinical trial partner you can be confident that we have the experience to understand your requirements and the expertise to make them happen.
**Why Vitalograph**

**Heritage and expertise**
Our clinical trials partners enjoy the peace of mind that comes from our 50 year heritage of researching, innovating and developing high performance cardio-respiratory devices which we have delivered and supported globally in clinical trials. Our success in providing high quality clinical trial data and operational efficiencies is reflected in the fact that the majority of our clinical trials work is repeat business.

**Customized software solutions**
Our experienced teams of software engineers are experts in developing optimized software solutions to meet your specific protocol and operational needs. This customization capability, coupled with flexibility, speed of response and personal service means we can provide systems that consistently deliver accurate data, on time and on budget.

**Cardio-Respiratory devices**
All our devices are designed, developed and manufactured in accordance with all relevant medical device standards.

**Global study experience**
With offices in the United Kingdom, United States, Ireland, Germany and Hong Kong, Vitalograph has delivered successful trials for many of the world’s leading pharmaceutical companies, biotech companies and contract research organizations, many of which have repeatedly chosen us as their clinical trials partner.

**Dedicated project team**
Our customized, personal service is made possible by our experienced and responsive team which includes dedicated project and data managers, software development engineers, internationally renowned over-readers, in-house QA and logistic specialists, plus full manufacturing and 24/7 support capabilities.

**International influence**
As one of the longest standing members of the ATS and ERS, together with our membership of other international respiratory organizations, we have well-established relationships with key clinical opinion leaders and academic institutions. These relationships drive our development strategy, allowing us to make valuable contributions to best practice in cardio-respiratory testing.
Services

Powerful centralized data capture
Vitalograph’s unique Spirotrac Software, in combination with expert over-reading, reporting and site training, maximizes overall data quality and reduces sources of variability or errors. Spirotrac provides standardized systems across all sites and can be customized for each study, with specific feedback tailored to the protocol to facilitate a wide range of measurements and data collection parameters including spirometry, DLCO, FENO, ABPM, Holter, cough, cardiac safety and patient reported outcomes (ePRO).

24/7 Global support
As a leading manufacturer of cardio-respiratory testing equipment and customized software, backed up with our global study experience, Vitalograph is well placed to understand the modern day challenges and logistical implications of running multi-national trials. Our expertise is complemented by a customer focused, 24 hour, multi-lingual support team trained in the specifics of each protocol in order to deliver the best help desk support for our partners.

Comprehensive expert training
Our expert training staff will design and deliver a custom training program focusing on the relevant testing guidelines and regulations, protocol specific testing and test quality requirements for your trial. Our training programs are designed to enhance technician proficiency, resulting in decreased risk of protocol infringements, improved data quality and higher confidence in your end-point measurements. Training can be delivered in person at investigator meetings, remotely or online.

Dedicated project management
Our project management expertise ensures that studies run to scope, schedule and budget, with ongoing assessment and management of risks. Each study is assigned a dedicated and skilled project manager supported by a project delivery team with experience in the conduct of cardio-respiratory clinical trials.

Fast, efficient reporting
Our project team is able to provide sponsors, CRAs and site staff with real-time custom reports from the centralized study database. Reports are delivered directly to site systems, via email or accessible online using the Vitalograph VIEWER web portal. Study specific metrics and data reports are available to sponsors at any time, by country, site and subject.

Consultation services
Vitalograph collaborates closely with a wide range of international cardio-respiratory experts and regulatory bodies on the development of performance standards and regulatory requirements for medical devices and the conduct of cardiac and respiratory testing. This expertise means we can offer guidance on the optimum data collection and logistical strategies to ensure a successful outcome for your trial.
**Rigorous systems and processes**

Our robust Quality Management System (QMS) is designed to protect the data integrity and success of your trial. Features include:

- Full compliance with ICH/GCP and ISO requirements
- Fully validated data management systems with built-in fail-over systems at multiple Vitalograph locations – everything is automatically backed up and continues to operate seamlessly in the unlikely occurrence of an unexpected failure of any individual system
- Automatic data back-up in all site devices including e-diaries
- Encrypted data transmission system – highly secure, fast and cost effective via the clinic’s broadband connection or via GSM from the patient’s home
- Web-based, on-demand access to data and reports – a powerful tool for monitoring the progress of your study using Vitalograph VIEWER

**Web services - PFT web capture system**

Our PFT Web Capture Systems allows for the electronic data capture of Lung Volume and DLco data at any site with specialist lung function equipment. Where study needs or budget constraints preclude standardized equipment or specific device training Vitalograph Spirotrac Software provides fast, secure, high quality data capture of most lung volume and gas transfer values supported by our powerful centralized QA review service. This versatile system can be tailored to suit the exact requirements of any primary or secondary endpoint.

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**Devices**

**Vitalograph cardio-respiratory clinical trials software devices**

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**Vitalograph Spirotrac Software**

Vitalograph Spirotrac® integrates high quality spirometry, 12-lead ECG, pulse oximetry, COPD assessment, blood pressure measurement, challenge testing and more in a flexible, integrated software solution.

**Vitalograph COMPACT**

The Vitalograph COMPACT™ Expert is a medical workstation that integrates high quality spirometry, 12-lead ECG, pulse oximetry, COPD assessment, blood pressure measurement, challenge testing and more in a flexible, integrated desktop medical device.

**Vitalograph asma-1**

The Vitalograph asma-1™ is a simple home use electronic respiratory monitor that measures PEF and FEV, and may be integrated with smart phones or tablets for ePRO data collection. It offers greater accuracy than mechanical peak flow meters and eliminates the need for paper record cards.

**Vitalograph In2itive eDiary**

The portable Vitalograph In2itive™ eDiary integrates data with Spirotrac to deliver home PEF / FEV testing or full office spirometry quickly and easily.

**Vitalograph AIM**

The unique Vitalograph AIM™ (Aerosol Inhalation Monitor) is designed to assess MDI or DPI use. Validation of satisfactory technique will support more accurate drug and dose delivery.
Vitalograph is a world leading provider of outstanding quality cardio-respiratory diagnostic devices, clinical trial services and medical equipment servicing. With a pioneering heritage of excellence spanning half a century Vitalograph continues to make valuable contributions to effective medical care and enhanced quality of life.