



the difference is clear

Your respiratory clinical trials partner

Our heritage

We at Vitalograph are proud of our 50 year heritage as a world leading respiratory specialist. Our pioneering spirit has led us to develop a number of innovative respiratory devices, including the first ever spirometer designed for use in primary care. This same commitment to innovation is reflected in our wide range of clinical trials services.

Vitalograph has been owned by the Garbe family since the day the company was founded. This continuity of management has resulted in a clear and consistent corporate vision; it has also created the reassuring stability and speed of response that comes from a financially strong, privately owned company with no influence from large corporate shareholders or venture capitalists.



Our expertise

Vitalograph is a leading global provider of respiratory products and services with offices and a network of expert distributors around the world. Vitalograph works in close collaboration with a wide range of international respiratory experts and is involved with CEN and ISO on the development of performance standards for respiratory measuring devices. In the last 5 years Vitalograph has provided 1 million clean test sessions from studies involving 1,110 sites and 40 countries.

Our people

Our people are committed to delivering the highest possible standards of customer care and are constantly seeking new ways to improve our service. In addition to friendliness, professionalism and flexibility our highly trained clinical trials team provides a breadth of experience in the delivery of multi-centred global trials, on time and within budget. They also have an in-depth understanding of ICH-GCP and the ATS/ERS requirements for pulmonary function testing in clinical trials.



Our services and equipment for clinical trials

We are committed to providing the highest level of service and equipment to meet the endpoints and measurement outcomes of your respiratory study, including:

- Centralized PFTs and data capture services:
 - Equipment rental or purchase for clinic and home based measurements
 - Spirotrac® spirometry and In2itive™ e-Diary
 - Integrated challenge testing
 - Integrated ECG services with over-reading by expert cardiologists
 - Integrated FeNO data capture
- VitaloJAK™ Cough Monitor
- QA Review by world-leading PFT experts to maximise data quality and provide detailed feedback on all tests
- Vitalograph PFT Web Capture System
- Complete data reporting including our secure web-based, on-demand, VIEWER™ Reports Portal
- Project and Data Management, including Protocol Review, Software Customization, 24/7 Support and Training Services
- Stand alone equipment for non-centralized studies

Our rigorous systems and processes

We have developed a wide range of sophisticated systems and processes to protect the security and success of your trial including:

- Secure data transfer of trial data from clinic or subject's home for home based spirometry recording and Patient Reported Outcomes
- Vitalograph recently passed its first routine inspection by The Medicines and Healthcare products Regulatory Agency (MHRA). The Agency reported zero critical findings and zero major findings. Vitalograph was one of only 5% of CROs to pass with this degree of success. In addition to this audit success, the latest FDA routine inspection of the Vitalograph research and manufacturing facility in Ireland was also a great success, again with zero deficiencies {483s} raised
- Mirrored data management system at a second Vitalograph location – everything is automatically backed up and continues to operate seamlessly in the unlikely event that the primary system fails
- Automatic data backup memory card in all Site Systems and in the In2itive e-Diary – making it simple to change in the event of a fault and to re-start with all data intact
- Encrypted Internet data transmission system – highly secure, fast and cost effective via a local broadband connection
- Web-based, on-demand access to data and reports – a powerful tool for monitoring the progress of your study using VIEWER

Project management

Our project management expertise ensures that studies run to specification and schedule and that all steps involved in successful completion are conducted with ongoing analysis and management of risks to GCP. Each study is assigned a dedicated project manager with several years experience in respiratory clinical trials. Project managers ensure that the following activities are tailored to suit the needs of each study:

- Study Management: to include project management, project analysis and reports to the sponsor
- Spirometry Consultation: to include protocol review and electronic quality review of pulmonary function tests and query resolution
- Data Management: based at Vitalograph Ltd, Buckingham, UK, this includes secure daily back-ups and a "mirrored" system at Vitalograph (Ireland) Ltd, Ennis; data edit checking and corrections; on-line (Web) monitoring and reporting

Spirotrac specialized centralized data services

The Vitalograph Spirotrac Centralized Spirometry System has been designed so that on receipt into our central database tests may be rapidly and regularly QA reviewed by expert over-readers. The database is then made available for edit checking, data transfers to the sponsor, and subsequent archiving. Different methods of connection can be made to the Internet to transmit encrypted data from investigator sites to the Vitalograph Centralized Data Management System, with all data collected at sites transmitted in this way. The intuitive Spirotrac software provides an easy to use, step-by-step work flow to collect data and is tailored for each study with protocol feedback. We also centralize full pulmonary function test services from diagnostic equipment for gas diffusion (DLCO) and lung volumes (TLC, FRC and RV), FeNO (exhaled nitric oxide) and other measurements.



Vitalograph reporting services from the data management system

Regular reports are provided from the central database via the Vitalograph Project Team, including:

- Pulmonary Function QA review
- Subject recruitment progress
- Subject alerts
- Site technician performance
- Subject visit status
- Subject compliance

Our reporting services are delivered either by email or via our VIEWER web portal. Reports of pulmonary function and subject diary data are provided to the sponsor so that monitoring of subject enrolment, progress of the study, subject compliance and alerts can be performed by CRAs and other registered personnel at any time, by country, by site, by subject.

Home based spirometry recording and ePRO

Vitalograph's pioneering In2itive e-Diary combines an integrated diagnostic quality spirometer, featuring a removable flow head, with an easy to use touch screen. This versatile e-PRO system is the first of its kind and can be customized for use in a clinical trial in a wide range of therapeutic areas and in any language. The device itself has a high resolution colour touch-screen, text based interface that accommodates validated questionnaires and is designed to comply with FDA's PRO Guidance. It is manufactured as a Class II medical device to a robust design that allows wireless data transmission using mobile



phone technology to send data securely from the subject's home for instant population of the study database. This system enables the study team to monitor and report upon the data in real-time using our on-demand reporting website, VIEWER.

Exhaled Nitric Oxide (FeNO)

In addition to our Centralized PFT Testing and Data Capture Services, we were the first company to integrate Aerocrine's NiOX MINO into our centralized spirometry system. This integrated solution transmits FeNO data together with spirometry, e-Diary and any other measurements collected via Spirotrac as a single dataset, to Vitalograph's Centralized Data Management System and from there to the sponsor. As well as capturing the data electronically, thus avoiding transcription errors, sponsors also like this integrated solution as they only require one vendor contract and one set of shipping costs and associated logistics.



VitaloJAK cough monitor

This unique product from Vitalograph embodies pioneering technology using dedicated HiFi recording, signal processing and expert algorithms to provide a 48 hour objective measure of cough in clinical trials. It provides an objective measure of cough in subjects with COPD, asthma and chronic cough, making it unnecessary to rely on time-consuming video, tape recordings or inaccurate subject diaries. Worn like a Holter monitor, with a single sensor affixed to the subject's chest wall, the VitaloJAK makes 48 hour cough monitoring simple. An optional second channel via a conventional microphone allows quality assurance with human intervention.

Spirotrac ECG

With the Spirotrac ECG software from Vitalograph, ECG measurements are captured and displayed in real-time, saved, recalled and printed. The software provides ECG analysis and interpretation based on the scientifically recognized Glasgow algorithm.

With the Bluetooth ECG BT12 device the 12-channel ECG data is wirelessly transmitted to the Spirotrac ECG Software. The built-in display provides information on electrode contacts, heart rate, battery status and telemetry reception.

All results captured by the Spirotrac ECG software are transmitted from clinical trial sites to the central server for expert review/over-reading.



Vitalograph USB, Serial and Bluetooth respiratory monitors

The Vitalograph range of USB, Serial and Bluetooth™ respiratory monitors is designed to enable transmission of respiratory data to your e-Diary, telephone, PDA, computer or telemedicine hub, making the home monitoring of those with chronic respiratory diseases, including asthma, cystic fibrosis, COPD and transplant patients, easier than ever.

These respiratory monitoring and screening devices are ideal for use in clinical trials where low cost yet accurate and reliable home respiratory monitoring is required.



Spirotrac Pulse Oximetry

Integrate pulse oximetry, 6 minute walk test and spirometry data.

Spirotrac Pulse Oximetry

The Spirotrac Pulse Oximetry Software Module allows you to plug an SpO2 sensor directly into any USB port on your PC to give accurate and high quality oximetry alongside spirometry. This optional module calculates, trends and reports all primary parameters including minimum, maximum and median SpO2/pulse rate. Capable of recording quick assessments or longer term recordings, with up to four transmitted values selectable by the user.



6 Minute Walk Test

- Spirometry and pulse oximetry data is automatically or manually integrated by the 6 minute walk test protocol
- 6 minute walk test Wizard runs in 10 logical stages
- Spirometry and pulse oximetry data is automatically or manually integrated by the 6 minute walk test protocol
- 6 minute walk test is a measure of disability e.g. in COPD studies
- The BODE* Index predicts COPD mortality based on FEV₁, 6 MWT, BMI, MMRC and Borg Scales (*Body Mass Index, Obstructive Index, Dyspnoea Score, Exercise Tolerance)

Training

The Vitalograph team provides training at investigator and monitor meetings with hands-on sessions and certification. Training can also be provided onsite with top-up training face-to-face or web-based. A range of training videos are also available via the VIEWER Web portal. Vitalograph offers full training of your project team to cover all relevant guidelines/regulations, protocol feedback and data quality prior to the study starting.

Global 24/7 support

Global 24/7 support is provided for sites and study monitors. Support can be provided in any language through the use of an expert interpretation service. Vitalograph maintains trouble-shooting procedures with a brief compiled for customer support personnel trained on the specific systems and procedures used by a given study. We have recently expanded Vitalograph's help desk and support network to allow provision of 24/7 support directly to subjects as well as study sites for all time-zones in over 140 languages. This new system utilises a global network of Support Technicians trained in both Vitalograph's devices and our sponsors' clinical trials. Vitalograph also offers a range of on-site equipment servicing options and calibration checks for longer studies.

Web services

PFT Web Capture System

This innovative web portal and electronic data capture system provides web services for effective monitoring of the study by study managers and CRAs. PFT Web Capture is designed to provide fast, secure data capture with centralized QA review without the need to invest in standardized high cost capital equipment or lengthy training. The system can be tailored to suit your exact needs and its versatility can meet the requirements of any primary or secondary endpoint. Vitalograph provides custom step-by-step software for each site to quickly complete a web page either on or off line. This data can include reports, graphs and images produced by equipment already in use at the site, whether electronic or on paper. The Vitalograph team in Buckingham, UK, checks that data entry from each site is correct before the new data is accepted into the central database on the web server. In this way clean data is captured throughout the study with fast data-lock after LPLV. Using the site's existing equipment gives a big

Device and software customization

Devices and software can be customized to meet the needs of a particular trial. The stages of customization include:

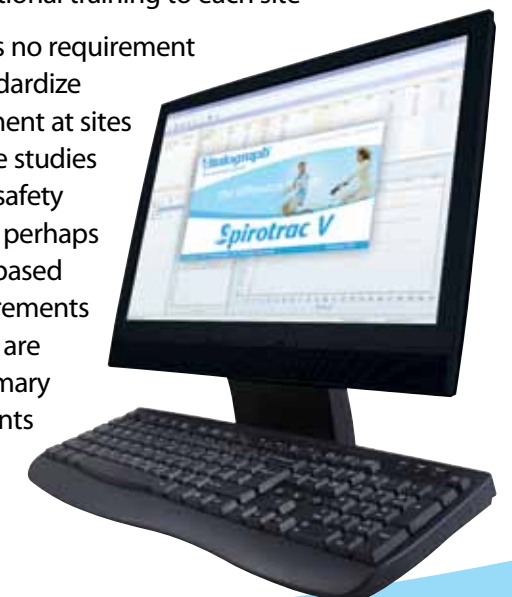
- Specification development and approval by the sponsor
- Software/device development
- Software/device testing/QA/validation
- Documentation
- Study documentation

By customizing the software, site personnel follow a workflow that takes them through each subject visit test type in accordance with the study protocol. This ensures that the protocol is correctly followed and provides a simple step by step approach to minimize site errors.

advantage for the study, including: low capital cost; no shipping logistics; faster PPFV; minimal training; higher quality data with automated transmission and error handling.

This new system is particularly valuable in trials where:

- You wish to monitor the quality of the site data without the need to provide diagnostic equipment or additional training to each site
- There is no requirement to standardize equipment at sites in those studies where safety data or perhaps home-based measurements or QOL are the primary endpoints



Regulatory compliance

Vitalograph systems and methodology conform to:

- ICH GCP
- FDA 21CFR Part 11
- FDA PRO Guidance
- HIPAA and 95/46/EC

Vitalograph's design and manufacture conform to:

- ISO13485: 2003 QMS for Medical Devices
- 21 CFR 820 FDA Quality System Regulation
- 93/42/EEC - L169 European Medical Devices Directive, as amended

Vitalograph clinical project management, customer support and device services conform to:

- ICH GCP
- ISO13485:2003
- ISO9001:2008
- FDA 21 CFR Part 11
- FDA PRO Guidance

Vitalograph works to detailed SOPs and study specific procedures in every clinical trial.

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.



Vitalograph Ltd.
Maids Moreton
Buckingham
MK18 1SW England
Tel: +44 1280 827120
Fax: +44 1280 823302
e-mail: pharma@vitalograph.co.uk
www.vitalograph.co.uk

Vitalograph GmbH
Rellinger Straße 64a
20257 Hamburg
Germany
Tel: (040) 547391-0
Fax: (040) 547391-40
e-mail: info@vitalograph.de
www.vitalograph.de

Vitalograph Inc.
13310 West 99th Street
Lenexa
Kansas 66215 USA
Tel: (913) 888 4221
Fax: (913) 888 4259
e-mail: vitcs@vitalograph.com
www.vitalograph.com

Vitalograph (Ireland) Ltd.
Gort Road Business Park
Ennis
Co Clare Ireland
Tel: (065) 6864100
Fax: (065) 6829289
e-mail: sales@vitalograph.ie
www.vitalograph.ie

www.vitalograph.com