

VITALOGRAPH CLINICAL TRIALS SERVICES



 **Vitalograph**[®]
Your cardio-respiratory partner

Data you can rely on. People you can trust.

CLINICAL TRIALS SERVICES

Vitalograph® has been a market leader in the design and manufacture of respiratory devices for over half a century. Our 50 year heritage of innovation enables us to respond effectively to the growing need for centralized cardio-respiratory data in clinical trials.

Created in 2003 our dedicated clinical trials team has grown from a UK-based provider of spirometry services into a multi-national organization providing centralized spirometry, home spirometry, e-diary questionnaires, centralized ECG, Holter monitoring and full lung function testing services.

- **Over 100** clinical trials completed
- **More than 1,300,000** sessions over-read
- Sites supported in **over 65 countries**

Services Overview

Vitalograph's services can be tailored to meet a wide range of study needs, from the smallest virtual biotech to the largest pharmaceutical company or clinical research organization.



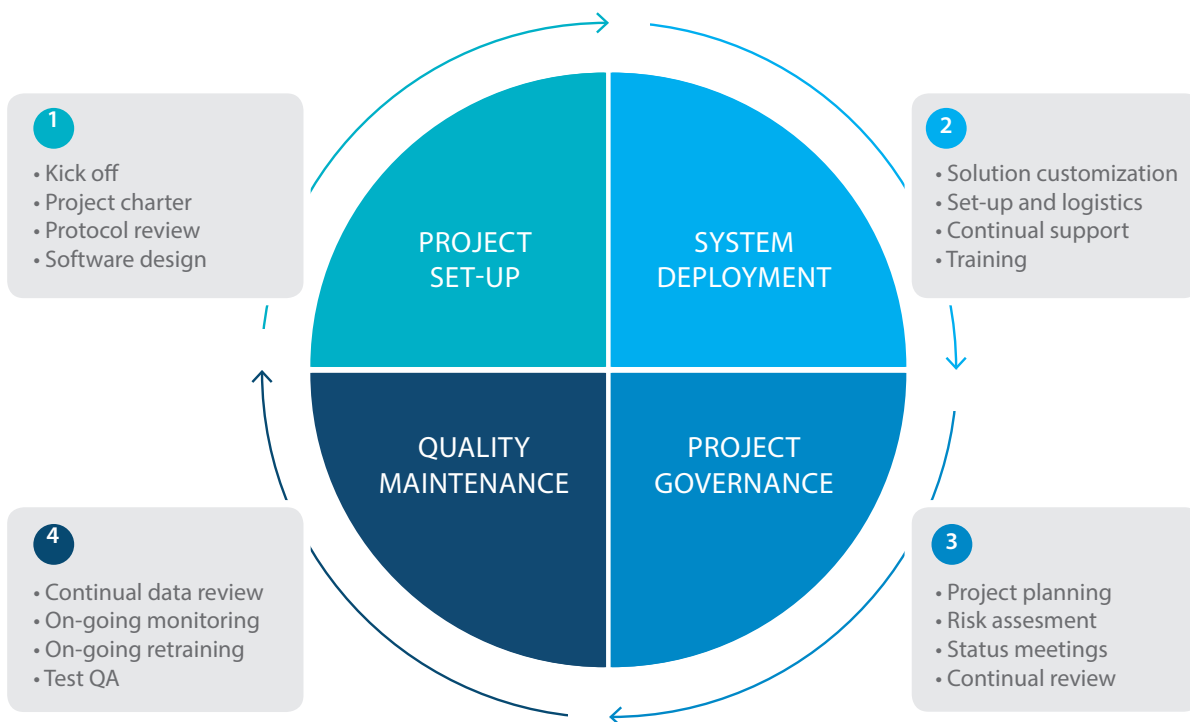
Project Management

Increased competition, stronger regulatory pressures and growing concerns regarding drug safety are making the clinical trials arena ever more challenging.

It is estimated that, on average, it takes more than 10 years and over a billion dollars to get a drug to market. Failure rates for early compounds are estimated to be around 85% and only 50% of those that make it to Phase III are approved.

With all these challenges it is important to select the right people to support your trial. Our expert study personnel around the globe will work closely with you to ensure that your trial runs ontime, to scope and on budget.

Project Management Process



All Vitalograph's processes are thoroughly documented in our comprehensive Standard Operating Procedures (SOP) and we are subject to regular audits and inspections by customers and regulatory bodies. This ensures our continued compliance with Good Clinical Practice (GCP) and regulatory requirements.

Expert Over-Reading Service

The ability to capture consistent and reliable data is an obvious but critical challenge within the clinical trials arena.

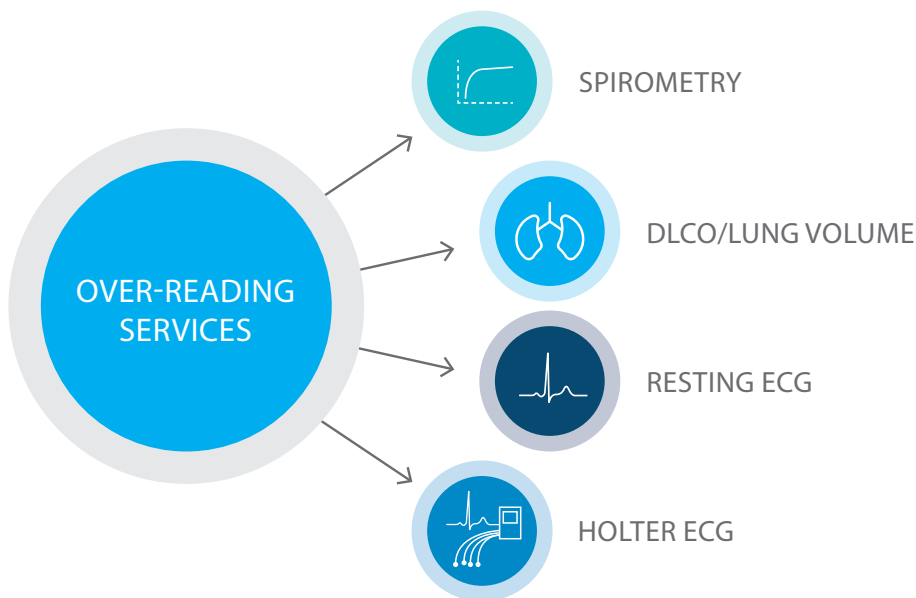
Whilst this challenge is common to all testing types it is most acute for tests that:

- Are highly effort dependent
- Require a high level of compliance and understanding by the patient
- Require competent coaching from the technician



Over-Reading Services

In response to this challenge Vitalograph has a team of expert over-readers who review the test results, confirm that the tests have been performed correctly and that they meet relevant guidelines and your study protocol. This ensures that only high quality data is submitted.



In addition to this, Vitalograph can have this data returned to you fully reviewed in under 24 hours* and provide you with comprehensive access to current and historical over-read data. When spirometry over-reading is employed we have seen the overall number of rejected testing sessions drop below 2%, allowing you to be confident in your spirometry data.

Our comprehensive training and standard over-reading services are sufficient for most trials, however, when decisions need to be made while the patient is on site, accelerated over-reading services are available.

* Standard turnaround times are 24 to 48 hours.

Protocol Consultation Services

The clinical protocol is one of the most important trial documents and plays a crucial role in ensuring its success. With over 50 years' experience in capturing respiratory measurements and over 100 trials completed, we are able to share our extensive knowledge with our sponsors.

Our protocol consultation service focuses exclusively on the cardiac and respiratory portions of your protocol, providing optimum recommendations in a number of areas including:

- ATS/ERS guidelines
- Device selection
- Parameter selection
- Visit scheduling
- Testing protocol
- Software alerts
- Technician training
- Over-reading practices



Software Customization

Our in-house specialist developers are able to offer customized software solutions for spirometry, FeNO, ECG, DLco, lung volumes and inhaler training, including:

- Protocol specific alerts
- Emailed alert reports
- Full integration with other Vitalograph solutions
- Compliance with ISO 13485, IEC 62304 and the technical requirements of 21 CFR Part 11

Data Management

Since 1980 Vitalograph has utilized PC-based solutions and, more recently, the Compact™ Medical Workstation to capture data electronically. These solutions are among the most advanced, secure and integrated data capture platforms in the industry.

Trial data is sent securely from our devices to our dedicated servers, hosted in our data centers. Vitalograph is able to deliver validated data sets in all common formats including SAS, ASCII and XML and is able to utilize CDISC conventions where required.

DLco/Lung Volume Data Capture

Vitalograph's revolutionary PFT Capture system enables us to capture and over-read lung volume data using sites' own equipment* thereby reducing costs significantly.

This specialized solution offers the same turnaround times as with all of our over-reading services. Centralized data management and reporting services are also available. The system can be tailored to meet the requirements of any primary or secondary endpoint.

* Not compatible with all equipment, device specifications available on request

24/7 Technical Support Helpdesk

Vitalograph 24/7 Support provides sponsors with peace of mind throughout the trial. Providing constant support we are able to ensure that 93% of all calls are answered immediately with the remainder being responded to within 10 minutes. Our technicians are fully trained on each study specific system ensuring sites queries receive a prompt and appropriate response.

Vitalograph is a world leading provider of outstanding quality cardio-respiratory diagnostic devices, clinical trials 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.

Investigator Training

Vitalograph offers comprehensive training to site staff and CRAs including:

- Hands-on training on the study system
- Equipment, systems software and support services overview
- How to identify good/bad test sessions
- CRA specific training, including equipment set-up
- Optional online video training to cover site personnel who cannot attend face to face sessions
- Certification of competency for use of our equipment/systems

Sponsor/CRO Training

The Vitalograph Clinical Trials Training Program is designed to assist pharmaceutical companies, biotechs and CROs in the effective running of a cardio-respiratory clinical trial. A bespoke program will be designed to meet the specific needs of your study.

This program includes:

- An overview of lung function testing
- Effective management of spirometry for clinical trials
- Lung function testing guidelines and considerations
- Differences between measuring technologies and devices

Global Logistics

Our extensive experience of shipping Vitalograph devices to hospitals and GPs in over 80 countries makes us well equipped to handle global logistics. Vitalograph's team of experts facilitates delivery of equipment, oversees re-supply and equipment returns and manages customs requirements.

Equipment Provision

A key factor in the success of any clinical trial is the quality of the data collected. This data quality relies on accurate, easy to use and reliable equipment. Vitalograph has over 50 years' experience in the design and manufacture of award-winning cardio-respiratory diagnostic equipment. For assessments not covered by our own equipment, devices from market leaders are carefully selected and integrated into our own systems.



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