

Delphic

STRATEGIC LABORATORY COMPANY

pharmacology pharmacogenetics virology

# the individualised care company

COMPANY OVERVIEW  
SCIENTIFIC EXPERTISE  
PROJECT MANAGEMENT  
DATA AND LOGISTICS  
QUALITY ASSURANCE

specialist laboratory company  
clinical research services  
pharmacology  
pharmacogenetics  
virology  
bioinformatics  
real-time and adaptive trials

# personalised medicine trial design



Delphic is a **specialist laboratory company** providing **clinical research services** to pharmaceutical companies, clinical research organisations and the healthcare sector. Established in 2001, the company has expanded organically and by acquiring specialist laboratories and diagnostics services giving it a combined history of 25 years in the provision of healthcare and clinical trial services.

## COMPANY OVERVIEW

Delphic specialises in pharmacology, pharmacogenetics and virology and is experienced in method development, method transfer and the design and development of trial protocols.

It developed as a strategic laboratory company to service the diagnostic needs of the healthcare sector; a market demanding scientific excellence and the ability to deliver results to clinically relevant turnaround times. It is now applying those skills to the design, management and delivery of clinical trials.

Delphic has specific clinical and scientific expertise in HIV, hepatitis and other infectious diseases. It is adept at managing and delivering both batch and routine testing as well as complex global clinical trials. Its comprehensive expertise in both pharmacology and pharmacogenetics makes it an ideal laboratory and management partner for adaptive trials.

- Pharmacology, pharmacogenetics and virology
- Method development and method transfer
- PK trial design
- Specialist biomarkers
- Genetic screening
- Batch testing
- Esoteric testing to rapid turnaround times
- Global clinical trials
- Specialists in HIV and hepatitis
- Bioinformatics and interpretative reporting

# method development / transfer

## clinical interpretation



Delphic specialises in pharmacology, pharmacogenetics and virology. It has extensive experience in method development, method transfer and the design and development of trial protocols. It has particular expertise in infectious diseases, including world-leading pharmacology and clinical excellence in HIV and hepatitis.

### SCIENTIFIC EXPERTISE

Delphic has the combined experience of over 150 clinical trials from inception and design through to bioanalysis and batched or clinical reporting.

Our dedicated pharmacology laboratory, acquired from and with continuing academic links to the University of Liverpool, has the scientific expertise and high-end instrumentation required to develop assays across most therapy areas, together with the ability to design PK studies and create interpretative algorithms.

The conjunction of our proficiency in pharmacology with our ability to develop biomarker assays gives our clients a competitive edge in the emergent market for adaptive clinical trials and personalised medicine.

#### Pharmacology

- Bio-equivalence studies
- Validated methods
- Drug/drug interaction studies
- Dose escalating studies
- Clinical interpretation / bioinformatics

#### Pharmacogenetics

- DMET Panel
- Genotyping
- Nucleic acid extraction
- Validated methods
- Customised pharmacogenetics and resequencing

#### Virology

- Genotyping
- Viral resistance
- Qualitative and quantitative viral load
- Flow cytometry
- Tropism

# total project management

## real-time results



Delphic has a project management team skilled in reviewing studies, applying scientific and clinical expertise to improve trial design and advising on current and new methodologies. The team oversees the design and development of protocols; plans and costs studies; coordinates review meetings; and, to ensure maximum sample-handling efficiency, can develop and run site training seminars.

### PROJECT MANAGEMENT

Delphic is a specialist laboratory company with world-leading expertise, high-end instrumentation, and laboratory and data management systems to GCLP, CAP and FDA specifications and guidelines. We provide both rapid batch testing and complex long-term studies requiring study design and algorithm-driven clinical reporting.

We are skilled in planning and trouble-shooting all aspects of clinical trial design and management, including contracting and managing sub-contracted services. We have excellent links with courier companies and have global reach with strategically placed sample reception centres.

- Dedicated Project Manager
- Develop study protocols from early clinical stage
- Review existing study design
- Advise on innovative technology and scientific methodology
- Develop a comprehensive trial delivery plan
- Recruit and manage sub-contracted services
- Coordinate data production and reporting
- Data exported in format to suit client database
- Integration with Oracle® Clinical, Clintrial™ or SAS®
- Coordinate and host review meetings
- Develop training and process documentation
- Run training seminars and workshops for investigators and site staff

# client integration

## bioinformatics



Delphic developed its sample and data management protocols and infrastructure in the time-critical environment of the healthcare sector. The company has invested in industry standard applications and in ensuring that all data is stored in a secure managed environment. All Delphic systems have comprehensive backup, recovery and contingency plans.

### DATA AND LOGISTICS

Delphic IT and sample-handling systems adhere to ICH Good Clinical Laboratory Practice (GCLP) and College of American Pathologist (CAP) guidelines in addition to the specifications of the US FDA, as laid out in 21 CFR Part 11.

Each trial database is designed to meet the individual needs of the client. We export the data from our bespoke, secure database environment in a format that best suits the client's receiving system, whether that is Oracle Clinical, Clintrial or SAS.

In addition to secure handling, storage and transfer of clinical data, Delphic also provides on-demand status reports on any given parameter, secure online access to trial related reports and secure data warehousing.

#### Data management

- IT systems to FDA specification
- SQL Server database servers
- Data exported in format to suit client database
- Integration with Oracle® Clinical, Clintrial™ or SAS®
- Clinical algorithms
- Status reports
- Data warehousing
- Statistics
- Bioinformatics

#### Sample logistics

- LabWare LIMS
- Courier contract and services management
- Sample collation and consolidation
- Integration with courier tracking systems

# quality assurance

Delphic has its own specialist laboratories and sample reception centres in the UK, and affiliate laboratories in Italy, Spain, Greece, Argentina and the US.

We participate in interlaboratory quality control and external quality assessment programmes and our UK laboratories are appropriately certified by EQA and NEQAS.

We apply our commitment to quality throughout the supply route expecting the highest quality standards from all partner laboratories and contracted services.

## Pharmacogenetics & Virology Laboratory

Delphic Laboratories  
Sittingbourne, Kent

- ISO 9001:2000
- CAP
- CLIA

## Pharmacology Laboratory

Delphic Laboratories  
Merseybio, Liverpool

- GCLP
- CAP
- CLIA

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