SIMBEC-ORION

Laboratory Services Supporting Clinical Trials Phase I-III

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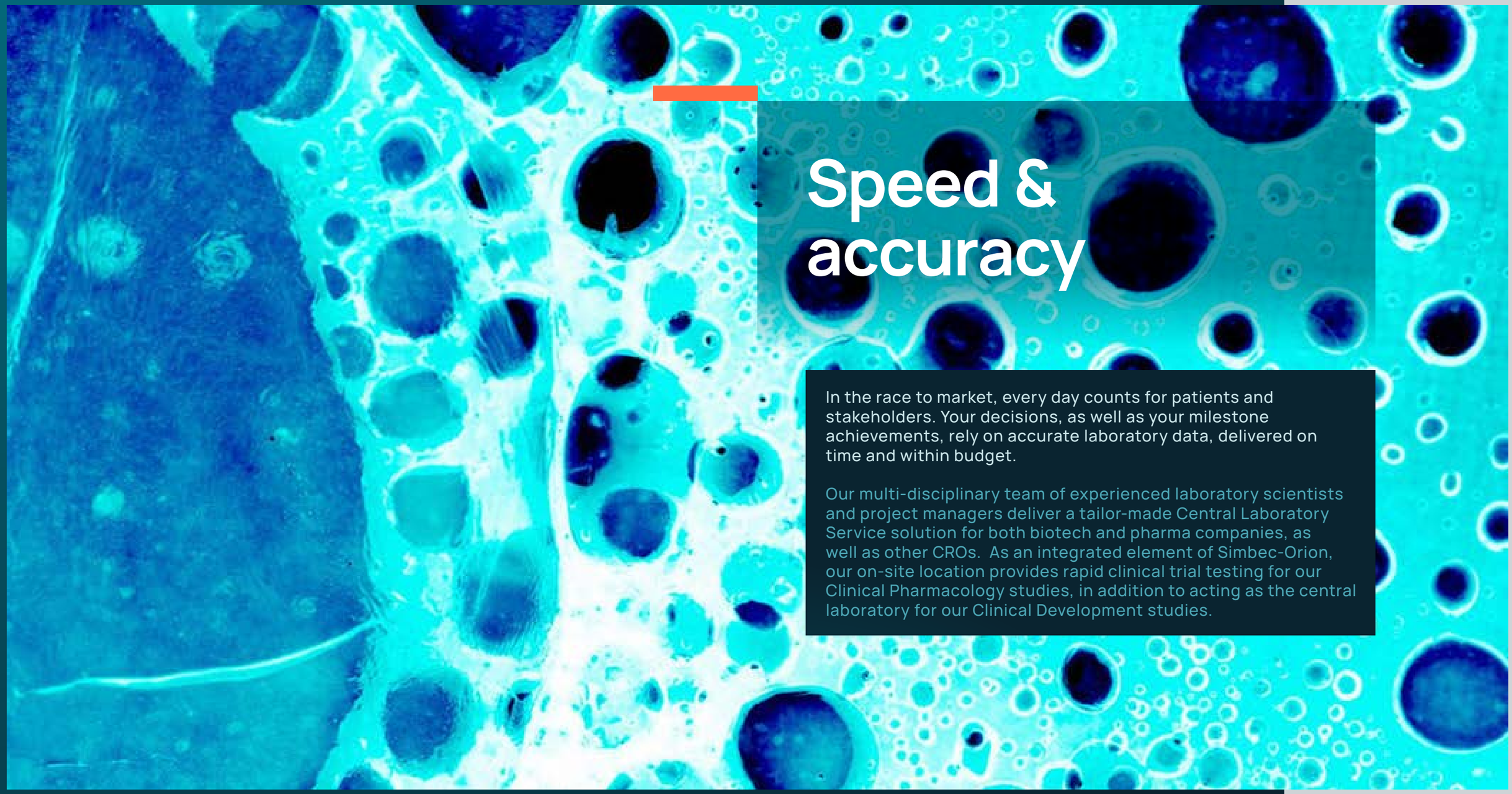

Speed & accuracy

In the race to market, every day counts for patients and stakeholders. Your decisions, as well as your milestone achievements, rely on accurate laboratory data, delivered on time and within budget.

Our multi-disciplinary team of experienced laboratory scientists and project managers deliver a tailor-made Central Laboratory Service solution for both biotech and pharma companies, as well as other CROs. As an integrated element of Simbec-Orion, our on-site location provides rapid clinical trial testing for our Clinical Pharmacology studies, in addition to acting as the central laboratory for our Clinical Development studies.

Phase I safety testing & phase II-III support

The central laboratories at Simbec-Orion provide clinical safety testing for early to late-phase clinical trials. Boasting a full range of instrumentation, our scientists provide both standard and bespoke assay panels, utilising a LIMS system designed specifically for the execution of clinical trials.

Standard and bespoke assay panels available

Industry standard analysers delivering accurate results

Fully integrated Laboratory Information Management System (LIMS), designed specifically for clinical trials

GCLP and GCP compliant labs

Phase 1 Clinicians on hand to consult

Specialised cellular techniques

24/7 Laboratory Support

Simbec-Orion laboratories are a multi-disciplinary service, offering expertise, gained over more than 45 years, from safety, pharmacodynamic and pharmacokinetic analyses, in support of phase I–III clinical trials.

- Over 45 years' experience
- Phase I-III
- On-site support
- Dedicated project manager
- PK & PD biomarkers
- GCLP compliant
- Bioanalysis
- Safety testing
- Sample management & logistics
- Quality driven

Laboratory services focused on what is critical to client support

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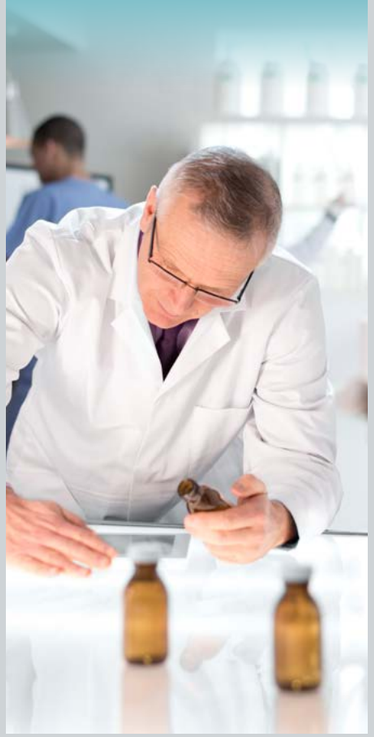
Experts in developing the most challenging of methods with subsequent validation to the required regulations. Utilising quality systems, we ensure that a robust, right-first-time approach is taken throughout.

Lab-quality systems



Driving right-first-time, lessons learned and process refinement.

Lab project management

Specialised Project Management in the lab ensures the projects are managed on budget, on scope and on time.

Innovation & development

Discovering the right solutions of the future and delivering scientific solutions in a digital world.

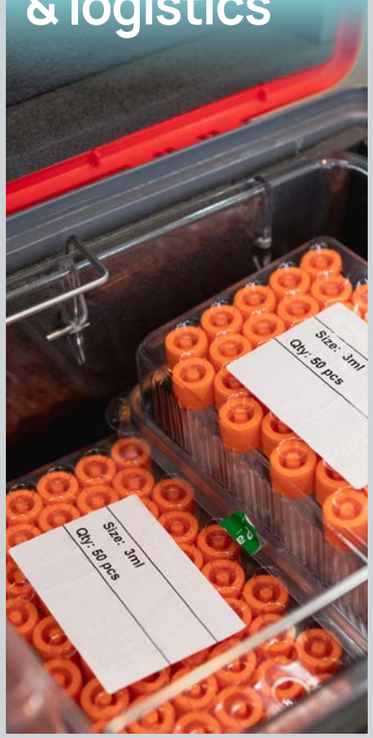
Bioanalytical & biomarkers lab

A versatile and knowledgeable lab that can deliver modern Bioanalytical solutions for our clients.

Safety labs

A high throughput lab with cutting-edge analysers delivering Pathology results to support our clients' trial.

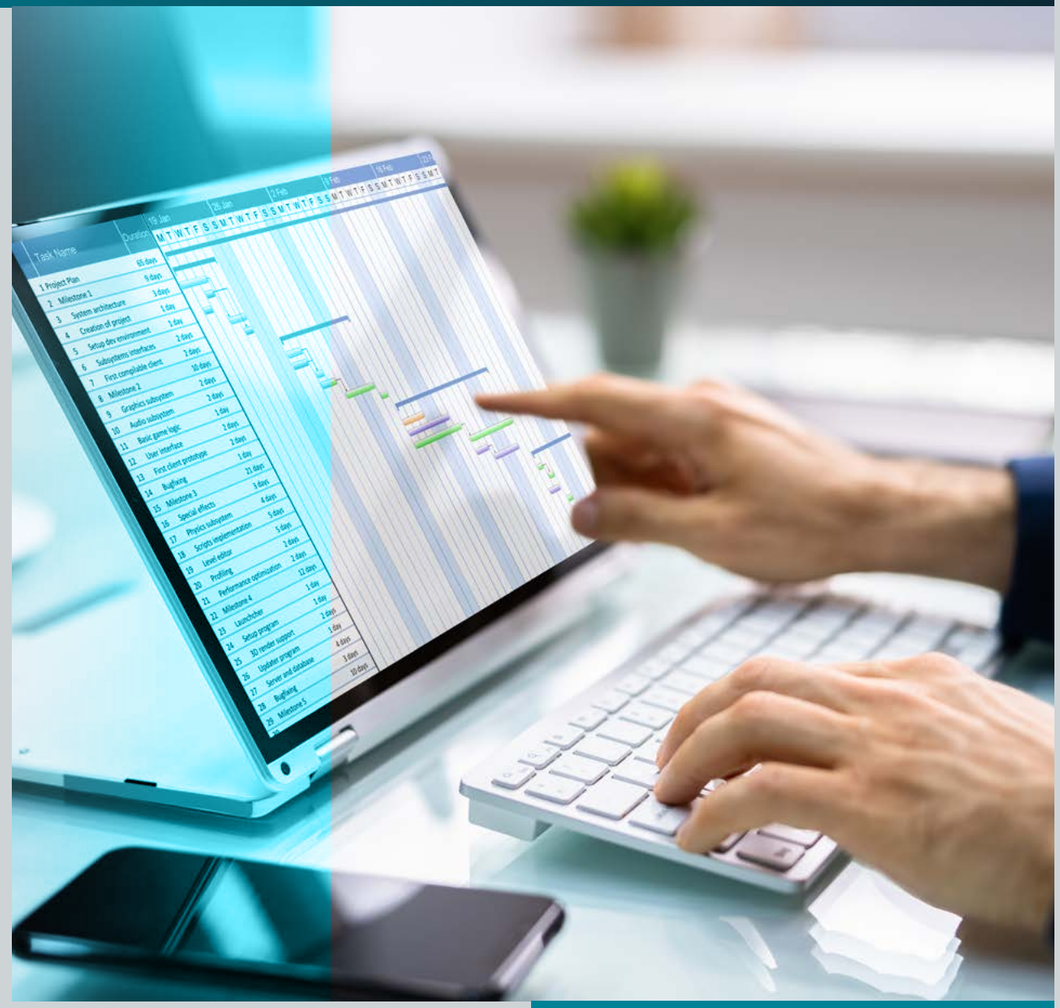
Sample management & logistics



Sample Management and Logistics team manage complex sample and kit shipping networks across the globe.

Laboratory project management

Increasing complexity in clinical trial planning and analysis, requires both experience and adaptability. Our dedicated laboratory project managers leverage our extensive experience managing a range of small to large clinical trials, to ensure studies are performed on budget, on time, and within scope.



Dedicated PM

Our client relationship focused, laboratory Project Manager (PMO) plays a pivotal role in leading and risk assessing all central laboratory operations.

Highly experienced

Extensive experience managing a range of small to large clinical trials. Ensuring studies are performed on budget, on time, on scope, as well as using high-quality project management systems and tools.

Future proof

In the last 5 years we have seen 20% year on year growth of study sample logistics requirements. We are constantly expanding to match this growth with the support of our dedicated laboratory project managers. Our focus is to succeed.

Quality driven

A laboratory quality management team lead by highly experienced staff. Working closely with project managers and quality systems, to ensure a high-level quality driven approach.

Dedicated to delivery

Rapid study set up

- Rapid set up, from Protocol to first patient
- Central Laboratory ready in just 12 weeks

Efficient study conduct

- On demand study supplies provided to sites in less than 10 days
- Study safety results turned around within 7 hours of sample receipt
- Flexible turnaround of study specialised analysis, built around client requirements

Customised documentation

- Study Specific Sample Handling Manual created using our years of clinical trial and laboratory experience
- Study sample inventory and requisition forms
- Laboratory Service Plan for clarity and transparency on our laboratory analysis land processing

Logistics are key

The increasing complexity in clinical trial planning and analysis requires both experience and adaptability. You can trust our experienced Sample Management and Logistics team to handle complex sample and kit shipping networks across the globe, whatever your study requirements.

- Central Labs Provider
- End To End Oversight
- Extensive Logistics Experience
- Varied Shipping Approaches
- Cost Conscious Approach

Our Sample Management and Logistics Team handles complex sample and kit shipping networks across the globe.

- Central Sample Receipt for all of your study samples
- End to end traceability through our Laboratory Information Management System, ClinAxys®
- Dedicated Central Laboratory Support Services (CLSS) members for study samples
- Robust sample query resolution process
- On-site or off-site sample storage options
- Full range of storage and shipment conditions, from ambient to dry ice and LN_2

Oncology

Rare & orphan

Anti-infectives & vaccines

Respiratory & airways health

Phase I healthy volunteers

Customised analytical solutions

Our combined skills and depth of expertise allows us to deliver customised analytical solutions, giving each of our clients a personalised, bespoke service most suited to the needs of their development program.

- Specialised cellular techniques
- Safety testing, biochemistry, haematology, urinalysis, coagulation, virology
- Flow cytometry for specific clinical indications and drug action
- Dried Blood Spot preparations
- LC/MS/MS Capabilities to support PK analysis including FIH, Bioequivalence, Bioavailability and DDI studies
- Immunoassay biomarkers for monitoring response of drug: single or multiple analytes
- PCR for the detection of infectious agents such as viruses and bacteria and used to support genomic testing

A partnership for success

The central laboratories at Simbec-Orion provide clinical safety testing for early to late-phase clinical trials. In addition to our in-house capabilities, we have established partnerships with trusted, local, innovative laboratories to support a range of specialised assay technology and additional capabilities.

In-house services:

- Standard and bespoke assay panels available
- Fully automated analysers
- Fully integrated LIMS designed for clinical trials
- GCLP and GCP compliant labs
- 24/7 laboratory support
- On site medics available

Provided through or trusted partners:

- Cell analysis and imaging to include Flow Cytometry
- Next Gen sequencing
- PCR
- Genomics
- Immunohistochemistry and In situ hybridisation

Scientific experience

The bioanalytical support for your study is directly managed by our highly experienced Principal Scientist, liaising with your clinical, pharmacokinetic, or bioanalytical teams. The same Principal Scientist oversees all aspects of your study from development, validation and study analysis giving consistency throughout the program.

Over 45 years' experience

With our experience we are experts in developing the most challenging of methods with subsequent validation to the required regulations. If needed, the team are also experienced in the transfer of methodologies from other laboratories.

You can be confident that we have the specialist knowledge of bioanalytical requirements for your clinical trials, providing technical support and early engagement with scientific advisors.

Our combined skills and depth of expertise of clinical trials allows us to deliver client solutions by offering a custom, tailored approach giving each client a personalised service.

The Laboratory provides a service compliant with “Guidance for Good Clinical Practice for Laboratories that perform the analysis or evaluation of clinical trial samples” (GCLP), and, as part of Simbec-Orion Clinical Pharmacology, are subject to mandatory Good Clinical Practice (GCP) inspections by the Medicines and Healthcare products regulatory Agency (MHRA).

In addition to the internal quality management systems, we participate in external QC schemes- UKNEQAS, WEQAS, SEQAS, LGC Proficiency which monitors acceptability of performance within the industry.

Our values

We are defined by our five core values and are committed to making Simbec-Orion a great place to work by building on these values to shape our company culture.

We reference our Values during our hiring and on-boarding processes. In this way, we are confident that we are recruiting like-minded individuals with values that align with ours.

By attracting the right talent to join a team already proud to work for Simbec-Orion, we strive to continue to make a difference. Both to the way we work, and to the lives of the patients waiting for new and improved therapies around the world.

We make a difference to people's lives - through the work we do and the way we do it. We make a positive impact on drug development for our clients and - most importantly - their patients.

We become an extension of your team, dedicated to your clinical development - whatever the challenges.

No matter what the problem. Or how big the challenge. Our dedication to delivery for you and ultimately patients, drives us every time without exception.

We're an agile team, willing and able to adapt to continuously changing circumstances.

Ethics and compliance are at the heart of what we do. So integrity is everything. We work with transparency, because that's the honest thing to do.

We are here to help with the next step of your clinical development

Simbec-Orion is a responsive and agile full-service CRO, with wide therapeutic experience and specialist expertise in clinical pharmacology, oncology and rare diseases. Perfectly structured, we provide full-service clinical development solutions for small and mid-size drug developers – headed up by a centralised leadership team.

With a focus on tailor made and scalable solutions, we'll adapt our delivery style, communications and operations to suit the demands of your project, helping you achieve your clinical and commercial objectives. Because our goal is the same as yours; to improve patients' lives.

Find out more at www.simbecorion.com or contact us at information@simbecorion.com

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