SIMBEC-ORION

Early Phase Research.
Delivering Complete Early Phase Research Needs From A Single Research Centre.

simbecorion.com

A long-standing reputation for excellence

Simbec-Orion's pharmacology centre has built a reputation of excellence across more than 45 years delivering clinical studies.

As one of the most well-established clinical pharmacology units in the UK, Simbec-Orion has the team, experience and an engaged network of volunteers for your study.

MHRA
Regulating Medicines and Medical Devices

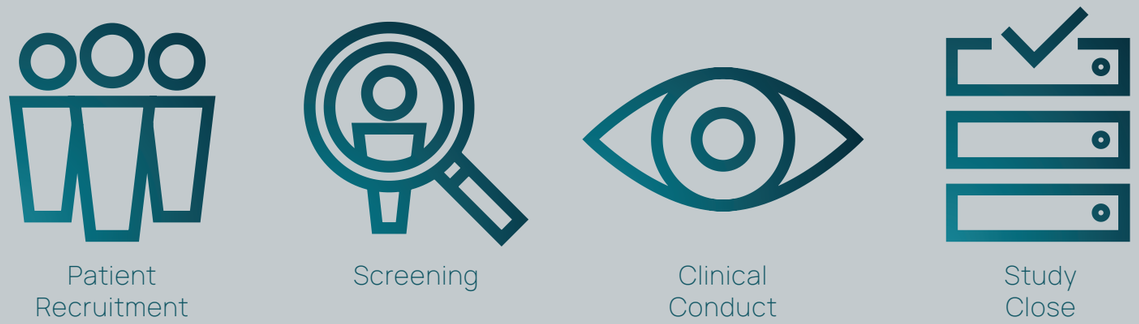
Quality-focused: Delivering results you can trust

Simbec-Orion is part of the MHRA Phase I Accreditation Scheme, and has carried out over 2000 clinical pharmacology trials, with all drug types, over more than 45 years.

Our extensive experience with the MHRA, EMA and FDA will add valuable insight to your clinical development plans.

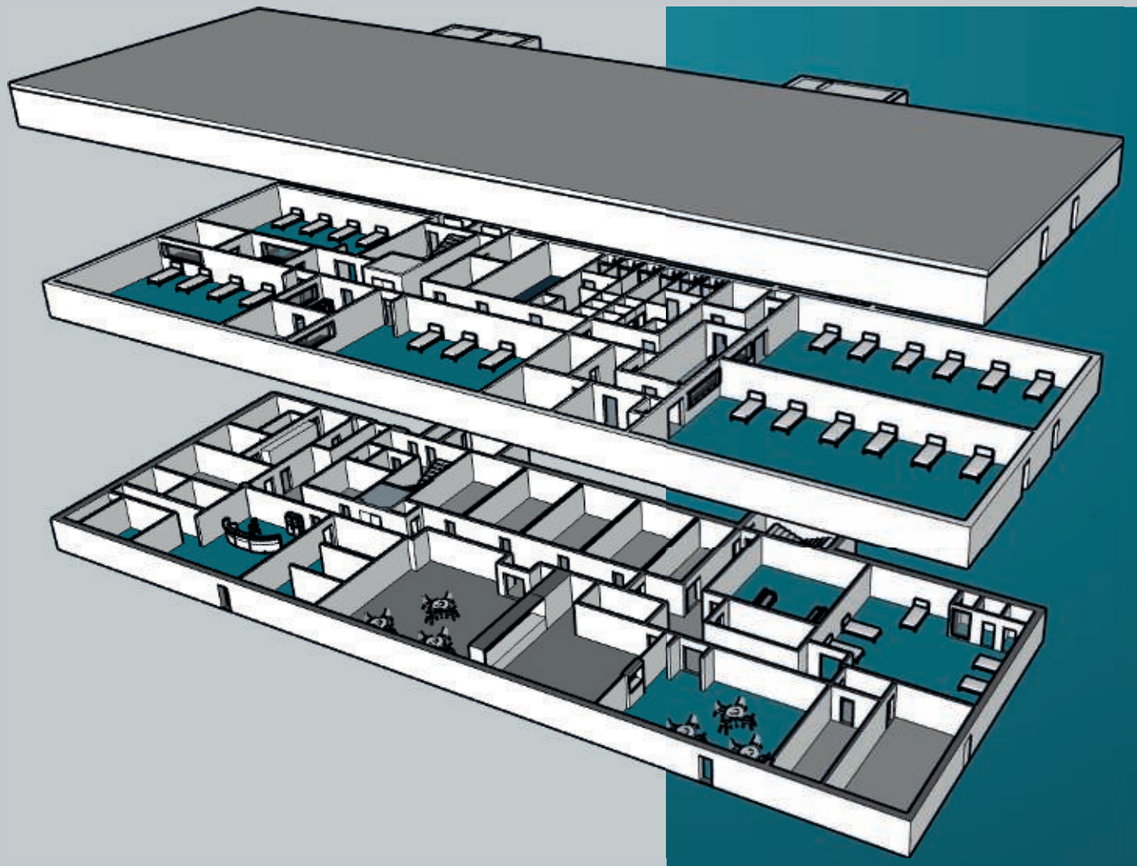
Seamless service, from start to finish

Our facility is designed to provide a seamless flow of clinical pharmacology services across the unit, from volunteer and patient recruitment to screening, clinical conduct, and on-site laboratories.



Established relationship with local Research and Ethics Committee for faster turnaround and approval decisions

A full-service clinical pharmacology unit, with co-located laboratory support



Second floor

- Laboratory Services (bioanalytical and pathology labs)

First floor

- 48 bed clinical pharmacology unit
- 5 wards
- Sample Preparation Laboratory

Ground floor

- Recruitment and screening area
- Day ward, 10 extra beds
- Respiratory chambers
- Support & catering facilities
- Pharmacy
- Scintigraphy

The team that delivers

Our experienced team has an agile approach to early phase research, with milestones in mind.

We believe our full-service clinical pharmacology unit is key to our success, but It takes more than just the right set-up to deliver results, it takes the right team.

Experienced leaders in the pharmaceutical industry, we ensure that our project timelines are competitive and resources are flexible. Our dedication to delivery is what ensures our clients return to us for our support at the critical early stages of clinical development. In the last 3 years, 50% of our early phase studies have been from repeat clients*.

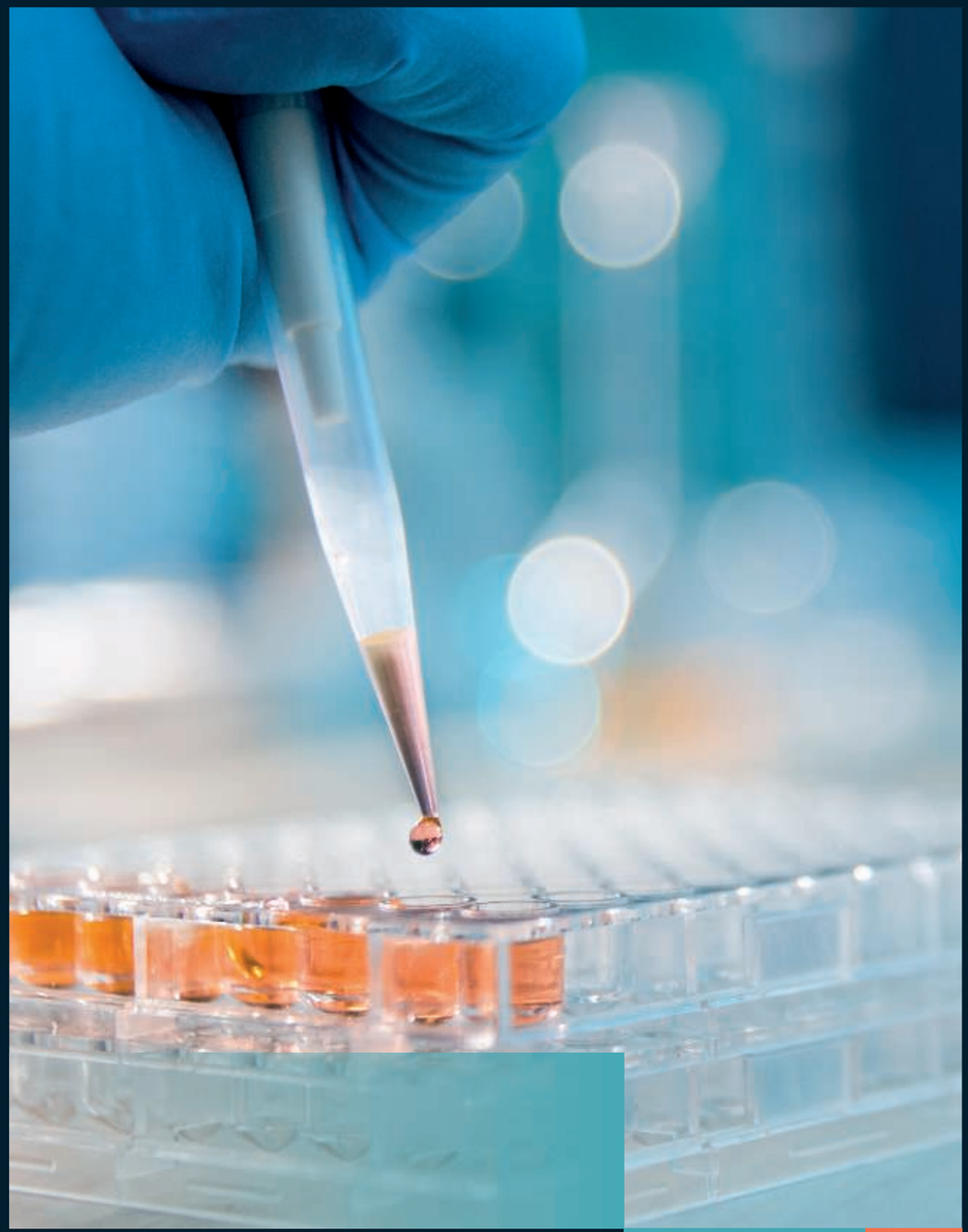
*Based on salesforce data extracted in November 2021

Clinical development services from beginning to end

Clinical pharmacology unit and head office situated in the UK, with local offices in France, the USA and Hungary.

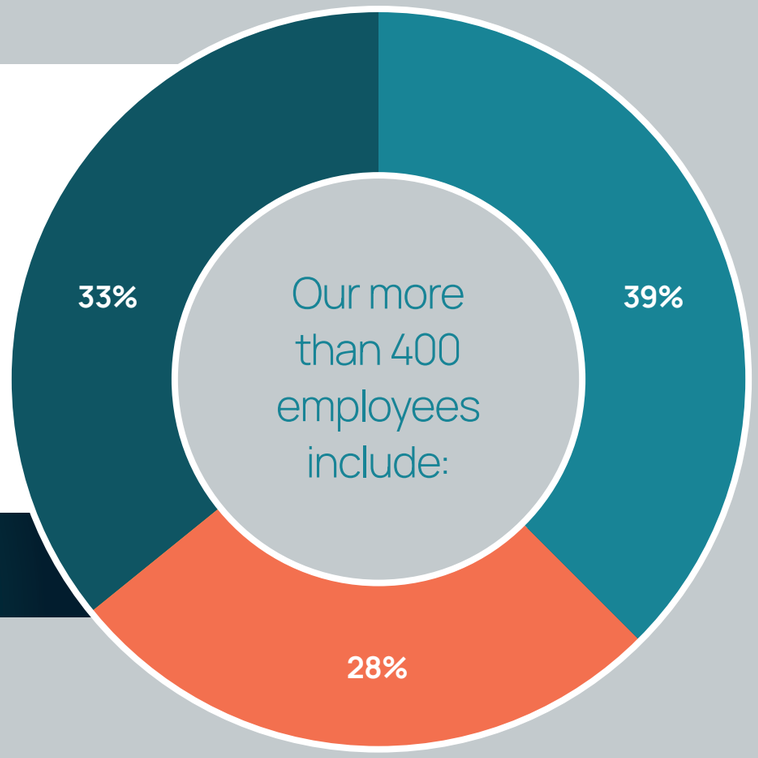
Over 45 years clinical pharmacology and labs expertise, over 25 years clinical development experience.

Clinical development division for an easy transition to the next step in your clinical development journey.



Services

- Experienced CRAs, CTLs, CTAs & PMs
- Bionanalyitcal, clinical pathology & IMP capability
- Support disciplines:
  - Biometrics
  - Regulatory affairs
  - Medical & technical writing
  - Pharmacovigilance



Pharmacology consultancy support

Experts in early clinical development with pharmacology consultancy available for protocol development and study support:

- Scientific Advice meeting support
- Review of non-clinical data & design of FIH studies
- Regulatory consultancy for Early phase/PK studies
- Phase I protocol synopsis development
- Due diligence of non-clinical and clinical/PK data
- Standalone non-compartmental PK analysis
- Early Clinical Development Plans
- Poster / Manuscript publication

Multi-site phase I Studies

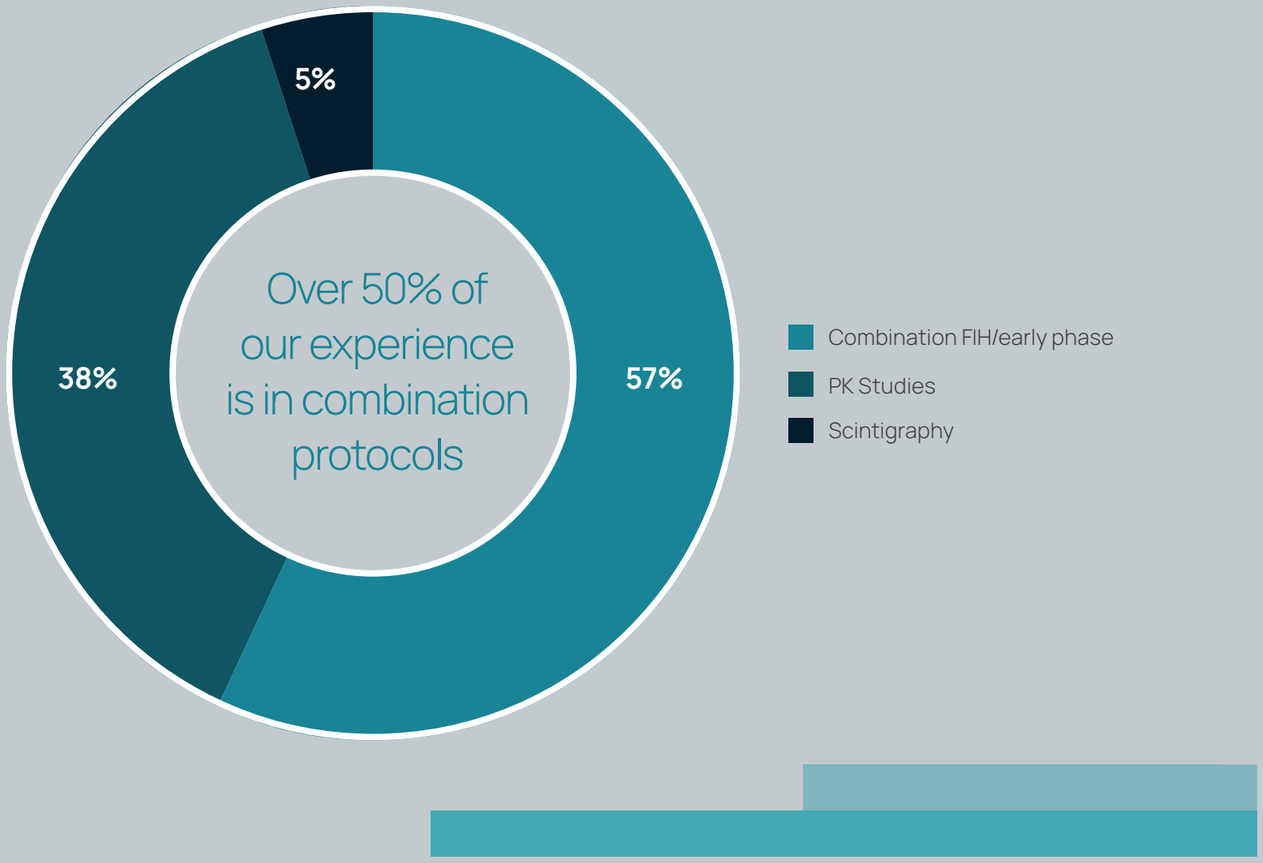
In addition to our stand-alone services, Simbec-Orion can collaborate with other Phase I sites to deliver multi-site protocols. Larger or long-duration Phase I studies can benefit from partnering with us and our established MHRA accredited partner sites to offer our combined experience and expertise on your study, in addition to a larger pool of volunteers for rapid recruitment.

A consultative service, with first-in-human, adaptive trial expertise

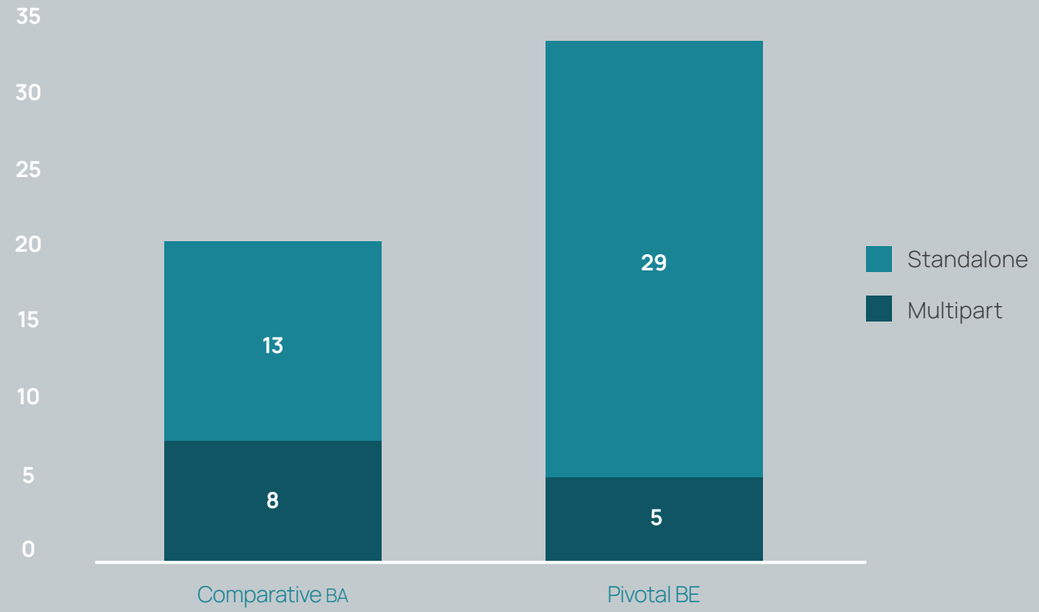
We have significant experience in First-in-Human trials with a strong focus on participant safety, risk management and adding maximum value to your protocol through adaptive trial design.

Using our knowledge and expertise, we advise on enhancements to your protocol development and study design approach, ensuring quality is built in from the outset to enable efficient delivery of your early phase results.

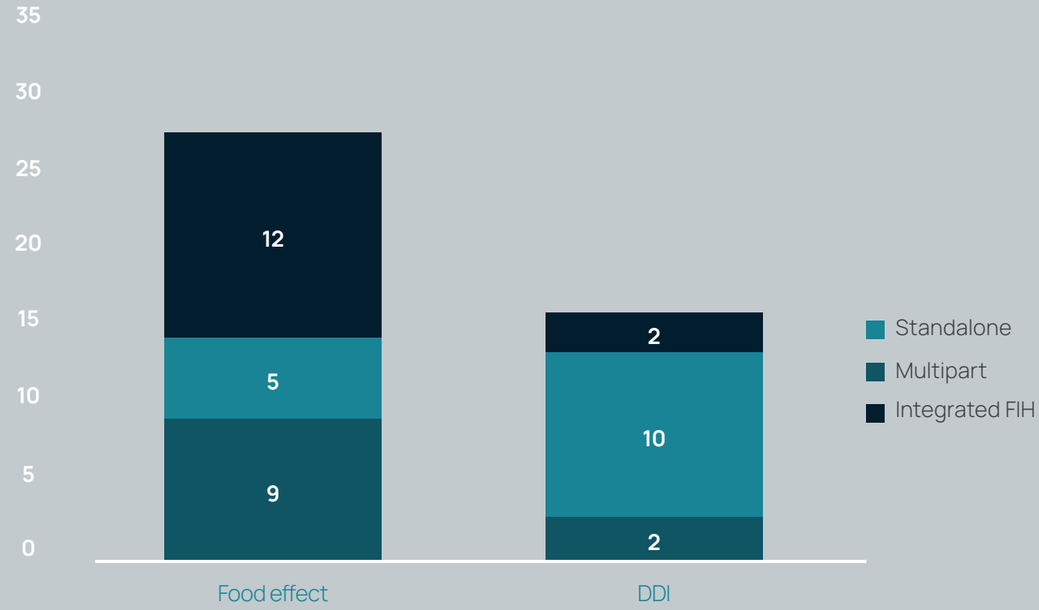
Recent study experience (last 10 years)



Pivotal BE & comparative BA studies



Food effect & drug-drug interaction study experience (last 10 years)



Scintigraphic data can inform critical decision making, optimising development programs and improving cost-effectiveness

Gamma scintigraphy can play a vital role in drug product development, facilitating the determination of the biodistribution of dosage forms under physiological conditions.

We have been working in partnership with gamma scintigraphy specialists, Cardiff Scintigraphics Limited, for over 25 years enabling us to provide seamless scintigraphy services for our clients. Gamma scintigraphy can be employed using our on-site dedicated dual head gamma camera.

A critical success factor is ensuring that the protocols are designed, and logistics of each dosing day carefully planned, to deliver high-quality results. Our approach is tailored to the specific objectives of the study, conducting planar scintigraphy scans to non-invasively assess regional or whole body radiolabel distribution.

Simbec-Orion clinical pharmacology has the teams, processes and volunteer pool to get enough appropriate volunteers for your trial quickly in a safe,cost efficient manner

Our Pharmacology Centre is within easy reach of cities, large population centres and universities. We are trusted by the local community and have built a reliable database of healthy participants and patients for your clinical study.

Extensive database catchment area

- Home of Simbec-Orion CPU
- Swansea - population **241k**
- Cardiff - population **350k**
- Newport - population **146k**
- Bristol - population **443k**
- Swindon - population **186k**
- Birmingham - population **1.1m**

At Simbec-Orion Clinical Pharmacology our in-house experts can work with you to ensure the data you want to collect can answer the questions you need answering. From development of the electronic Case Report Form (eCRF) through to PK analysis.

In addition to routine PK analysis for demonstrating bioequivalence, we offer rapid turnaround of PK analysis for dose escalation decisions.

Tailor-made laboratory service solutions from theheart of our clinical pharmacology unit.

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-campus location provides rapid clinical trial testing for our Clinical Pharmacology studies, in addition to acting as the central laboratory for our Clinical Development studies.

With more than 45 years' experience, we are 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.

Laboratory services focused on what is critical to client support

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.

Lab Innovation & Development

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

Bioanalytical labs

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

Pathology labs

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

Sample management and logistics

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

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.

Through our partnerships we can support:

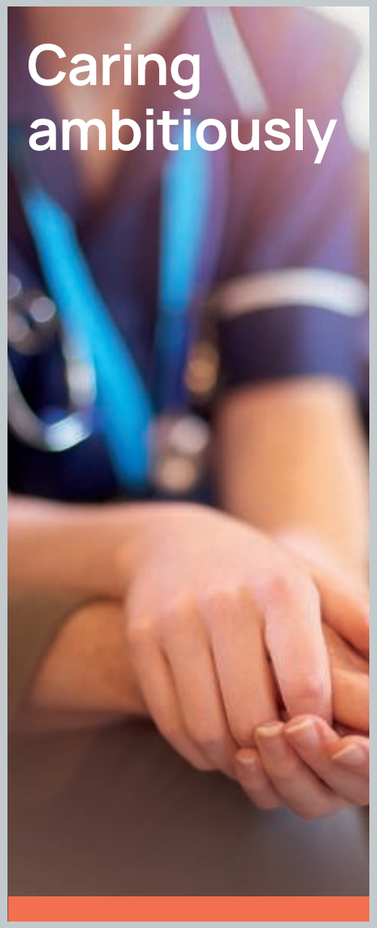
- Cell analysis and imaging to include Flow Cytometry
- Next Gen sequencing
- PCR
- Genomics
- Immunohistochemistry and In situ hybridisation

Our values

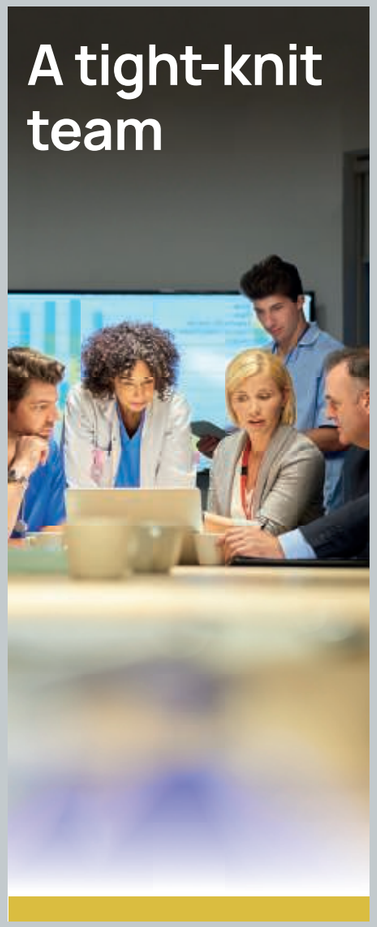
We are defined by our five core values and are committed to making Simbec-Orion a great place to work by building on these values to shape our company culture.

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.



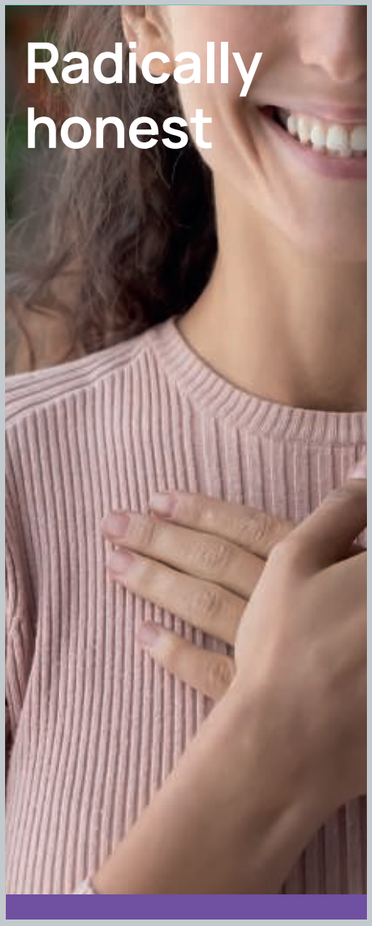
We make a difference to people's lives - through the work we do and the way we do it. We make a positive impact on drug development for our clients and - most importantly - their patients.



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, rare disease and rare oncology. 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 tailormade 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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