SIMBEC-ORION

Clinical Development Study Support.

Broad Therapeutic Experience. Experts in Oncology, Rare Disease and Rare Oncology.

simbecorion.com

Working with unique challenges

We've encountered many unique challenges that hinder complex hospital-based studies, including rare diseases and oncology trials.

As a full-service CRO of our size, we're ideally placed to meet a diverse range challenges head-on.

From maximising site selection to forming close links with patient advocacy groups, and enrolling patients, we overcome hurdles to help medicines to market.

The Simbec-Orion infrastructure

Head office situated in the UK, with local offices in France, the USA and Hungary.

More than 25 years clinical development expertise.

A quality-focused approach ensuring data integrity and patient safety.

Supporting clinical studies from phase I in volunteers or patients

- Dedicated 48 bed phase I facility
- Pharmacovigilance group
- Regulatory group
- IMP management group
- Consulting team

Central laboratory services and logistics

- Central laboratory services
- Bioanalysis
- Central laboratory network
- Safety testing

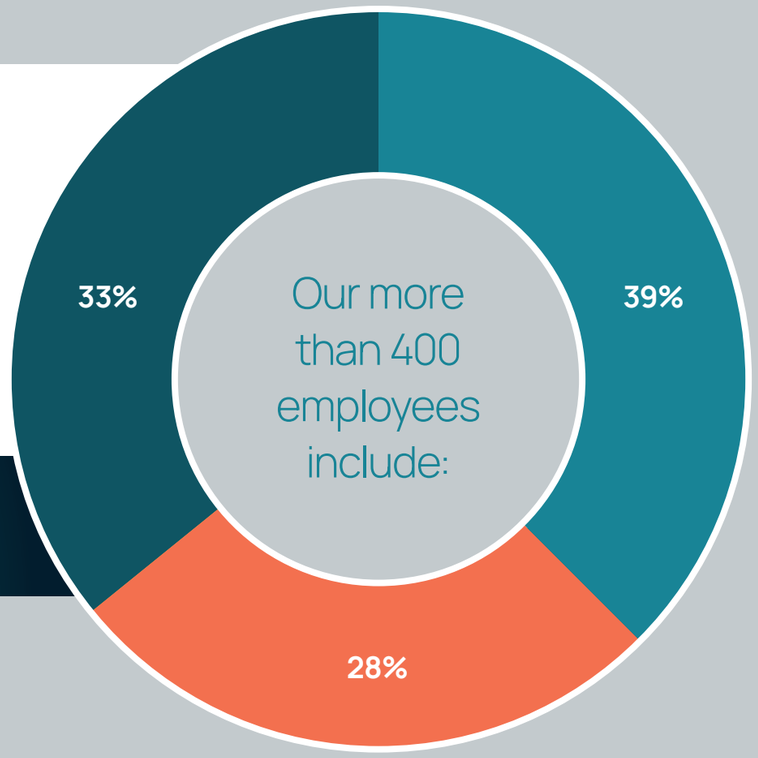
A full-service clinical pharmacology unit, with everything in one place

- Laboratory Services (bioanalytical and pathology labs)
- 48 bed clinical pharmacology unit
- 5 wards
- Sample preparation laboratory
- Recruitment and screening
- Day ward, 10 extra beds
- Respiratory chambers
- Support & catering facilities
- Pharmacy
- Scintigraphy

The right-sized CRO, with international reach

Services

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



Scientific advisory board with expertise in oncology & rare disease studies

The Simbec-Orion Scientific Advisory Board (SAB) is established to offer our clients additional support and guidance in our core therapeutic areas of rare disease and oncology, including rare oncology. The SAB consists of experts in their respective fields with extensive experience in:

- Clinical development
- Scientific consultancy
- Complex protocol design
- Orphan drug designation
- Paediatric investigational plans
- Marketing authorisation applications by both the EMA and the FDA

Your international team

With four main offices in the UK, Europe, and the USA, as well as operational teams more widely located throughout Europe and North America, we have the global reach to deliver studies in every region and across multiple timezones.

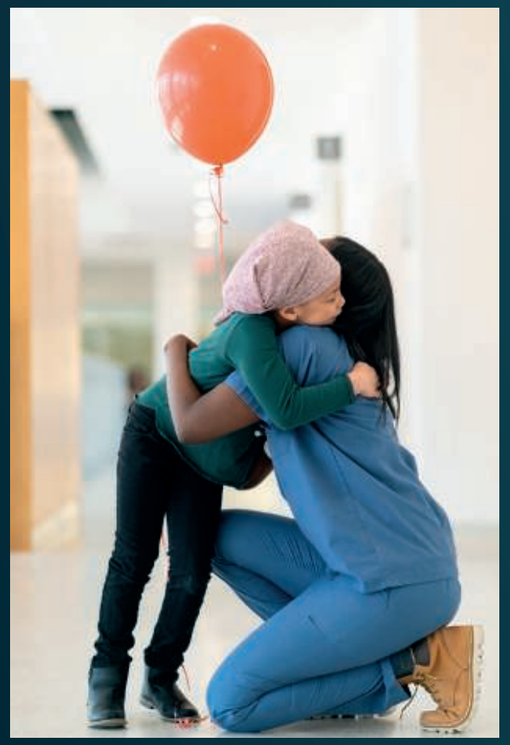
Pharmacology consultancy support

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

A patient-centric approach

Every patient is unique – we understand this more than most. We endeavour to ensure studies are designed with patients' needs front and centre.



Deep therapeutic experience

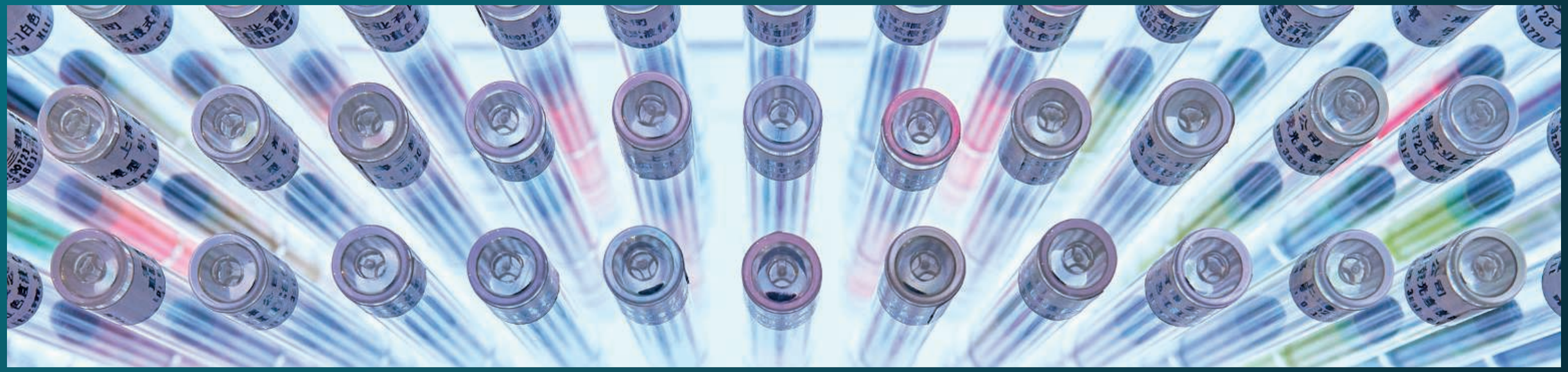
Over 25 years clinical development experience has given us a wide range of experience across a broad range of therapeutic areas.

Quality-focused

We are dedicated to expertly delivering your study – supported by our extensive experience, robust strategies and quality-first focus.

Agile and resilient

Our size and structure allows us to rapidly respond to challenges. Our lean management structure means we are able to escalate issues quickly when required.



What we offer:

Phase I-IV services:

We deliver the full range of clinical development services you would expect from a large CRO, with the structure and size to offer personalised, tailor-made solutions. Delivering a integrated and responsive approach to mitigate risk and smooth the path to your next milestone.

- Project management
- Regulatory affairs
- Consulting & strategic support
- Clinical monitoring
- Central laboratory
- IMP management
- Medical & pharmacovigilance
- Biometrics (data management & statistics)
- Technical writing
- PK/PD studies
- Bioavailability & bioequivalence studies
- Bioanalytical laboratory
- Scintigraphy
- Scientific advisory board (SAB)

Caring ambitiously

Caring ambitiously is one of our five core values. 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.

Efficient & transparent project management

We're a low hierarchy operation and we believe in getting the job done, efficiently and with transparency. Your dedicated project manager will drive the project from start to finish, with access to the senior management team for face to face troubleshooting.

Our CRAs are decentralised, meaning that they are located close to clinical sites, enabling them to facilitate close communication which drives patient enrolment and site management.

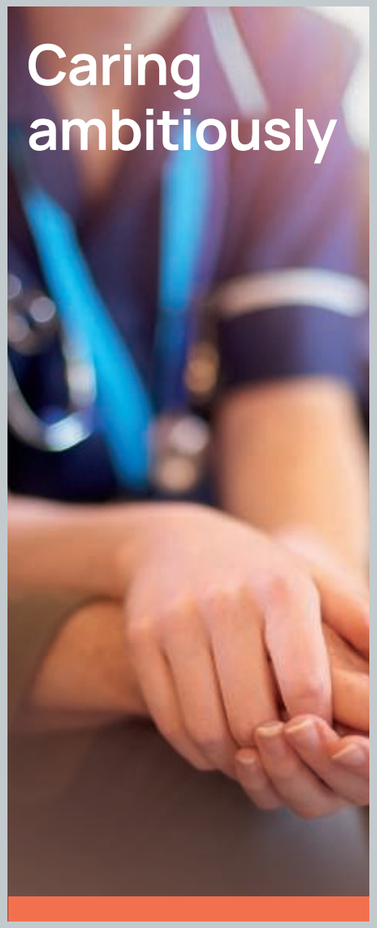
With strong governance and project escalation communication plans in place from day one, we mitigate risk and work around any obstacles that may arise. We understand that complex studies evolve and may require a change in scale or flexibility. Our team is responsive when your study needs it.

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.



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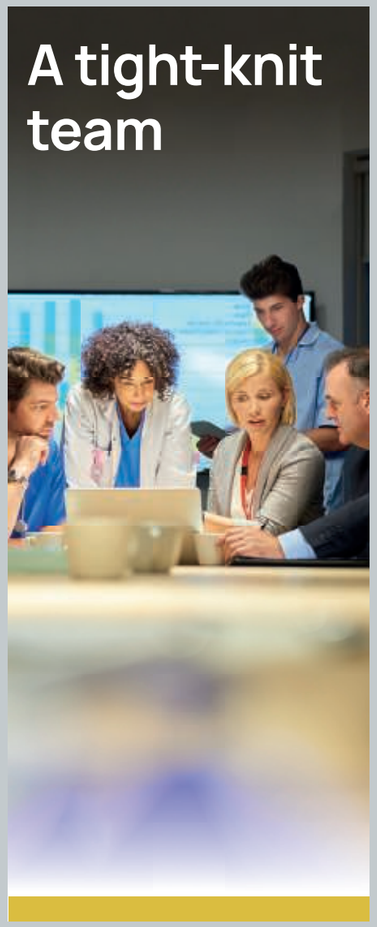
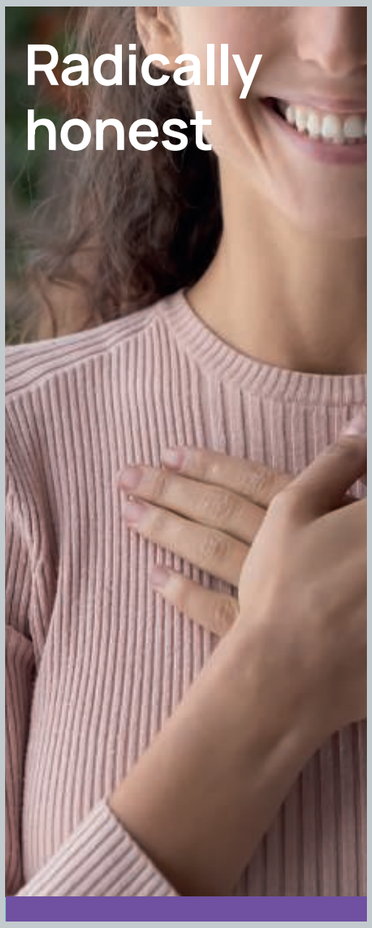


We become an extension of your team, dedicated to your clinical development - whatever the challenges.

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.

Over 25 years delivering clinical development studies from phase I-IV

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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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