SIMBEC-ORION

Company Overview

simbecorion.com

Full service CRO

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 tailormade and scalable solutions, we adapt our delivery style, communications and operations to suit the demands of our clients' projects, helping achieve clinical and commercial objectives. Because our goal is the same: to improve patients' lives.

Clinical development services from beginning to end

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

More than 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.

Our service network

Supporting clinical studies from phase I

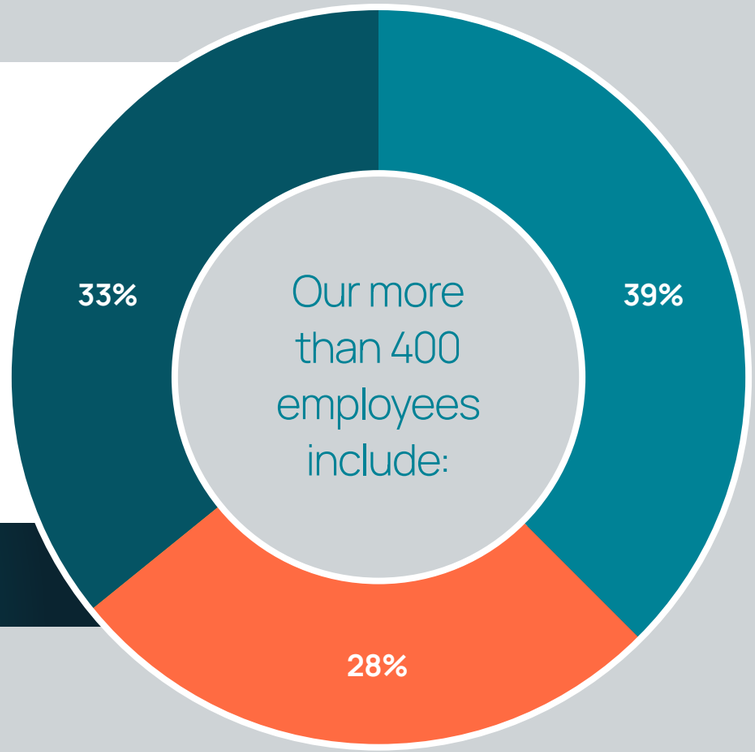
- Dedicated 48 bed phase 1 facility.
- Pharmacovigilance group.
- Regulatory group.
- IMP management group.
- Consulting team.

Central laboratory services and logistics

- Central Laboratory Services.
- Bioanalysis.
- Central Laboratory Network.
- Safety testing.

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 and 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.

Full service CRO offering

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)

Extensive experience

- Built and dedicated to serve the Biotech sector in EU + US.
- Unique combination of pharmacology FIM and oncology & rare disease expertise in highly complex indications.
- Focusing on building long-term relationships with both sites & clients, based on trust, delivery and compliance.
- Fully integrated services and systems.
- We understand the challenges in Biotech clinical development.

Robust strategy

- Act as our client's ambassador by partnering with sites for PI engagement and patient recruitment.
- Stable Team – dedicated to investment in our people.
- Clear and proactive methodology to optimise recruitment of patient in cohorts.
- Global Advisory Board to add strategic value to the project.
- Transparent communication and reporting.

Efficient execution

- Capitalise on privileged relationships with key sites to accelerate set-up.
- Focus on Data Integrity (ongoing medical & safety review, and data cleaning).
- Governance structure implemented to meet both project and corporate goals.
- State-of-the art technology platform.
- Proactive, Agile, Flexible.

An integrated and responsive approach

Early phase research facility

Part of the MHRA Phase I Accreditation Scheme, our purpose-built UK facility is designed to deliver a seamless flow of services across the unit.

Led by scientific knowledge and stewarded by Principal Investigators who have dedicated their research careers to clinical pharmacology, our clients can be sure their study is in safe hands.

Experienced laboratory services team

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.

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.

Seamless transition to later phase

As a full-service CRO. we will design and deliver clinical development projects shaped around your unique requirements.

Agility and resilience

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.

Global collaboration

We have extensive experience collaborating with a wide range of sites, not only across Europe and North America, but also within Asia, South America, and Australia.

Experts in rare and orphan studies

We have a deep understanding of rare diseases including paediatric studies from our 25 years experience. More challenging than trials in common diseases, adaptability and resilience is crucial to delivery success.

There are many unique challenges with complex rare disease studies. As an experienced full-service CRO of our size, we're ideally placed to proactively manage study challenges.

Maximising site selection and forming close links with patient advocacy groups in support of patient enrolment, overcoming hurdles to help medicines to market.

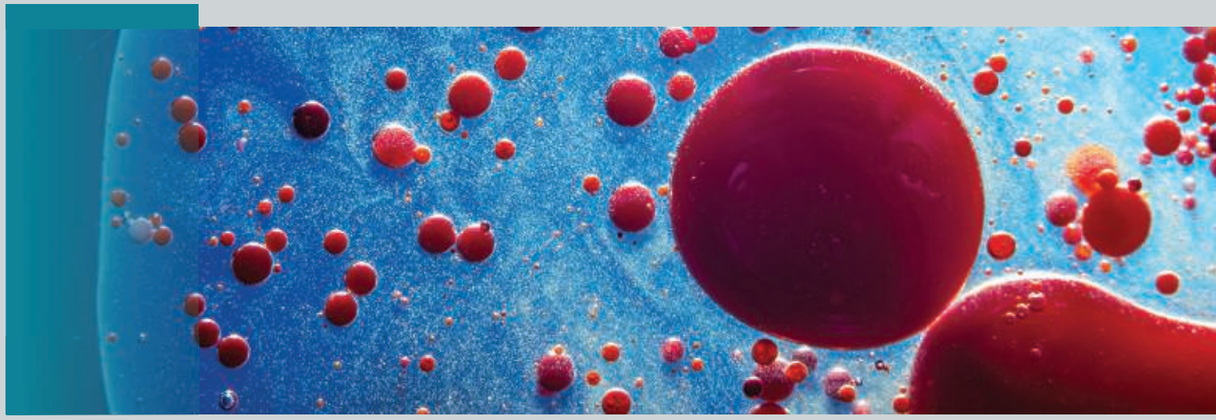
We are focussed on patient-centric trials and novel designs to help improve patient lives, supported by our rare disease advisory board.

Experts in oncology studies

With 25 years' experience delivering oncology studies, we know that oncology drug development requires flexibility, determination and engaged investigator sites supported by our clinical management. Approximately 47% of Simbec-Orion's experience is oncology focused across many indications in this area.

Our experience in conducting Phase I/II adaptive oncology clinical trials, through to Phase III studies has given us a deep understanding of managing complex hospital-based studies, supported by a world-leading oncology advisory board.

Our experienced CRAs are trained on the specifics of your study protocol. CRAs are regionally based, providing a flexible, cost-effective and fully integrated approach.



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.

2022 Simbec-Orion charity of the year

Beacon (formerly known as Findacure). Beacon is a UK-based charity that is building a united rare disease community with patient groups at its heart. Beacon up-skills rare disease patient groups through training, guided programmes, community projects and research initiatives, helping them maximise their impact and deliver change for the world's often neglected rare disease patients.

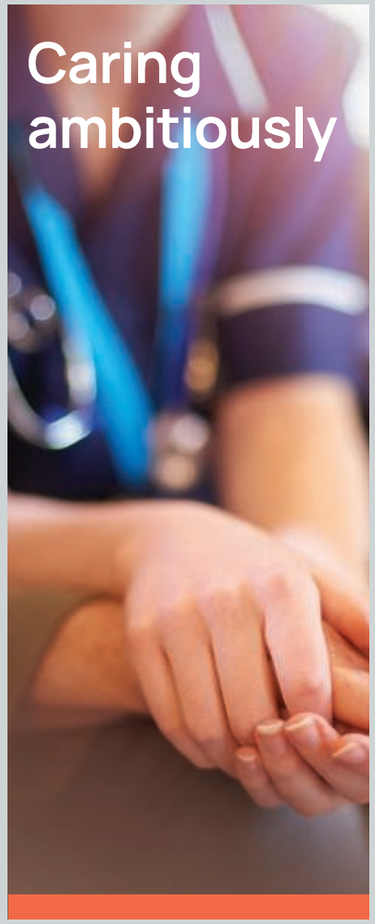
SIMBEC-ORION | beacon for rare diseases — no rare journey alone

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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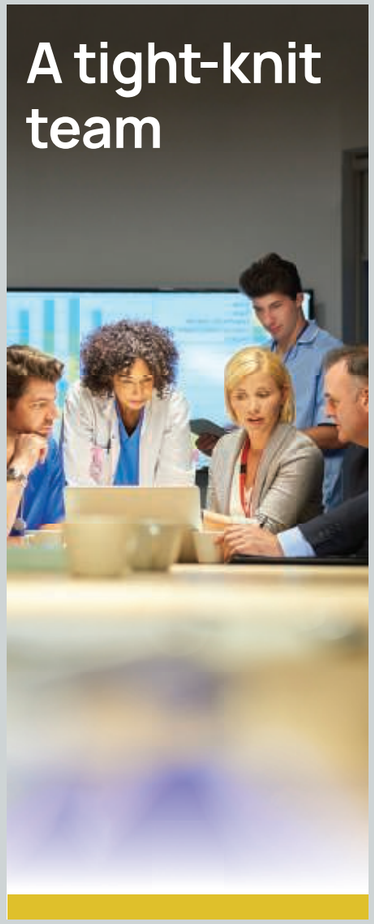
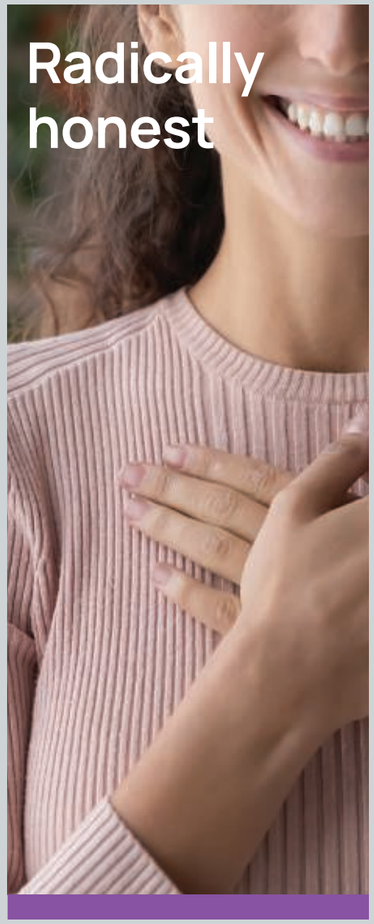


We become an extension of your team, dedicated to your clinical development - whatever the challenges.

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.

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

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