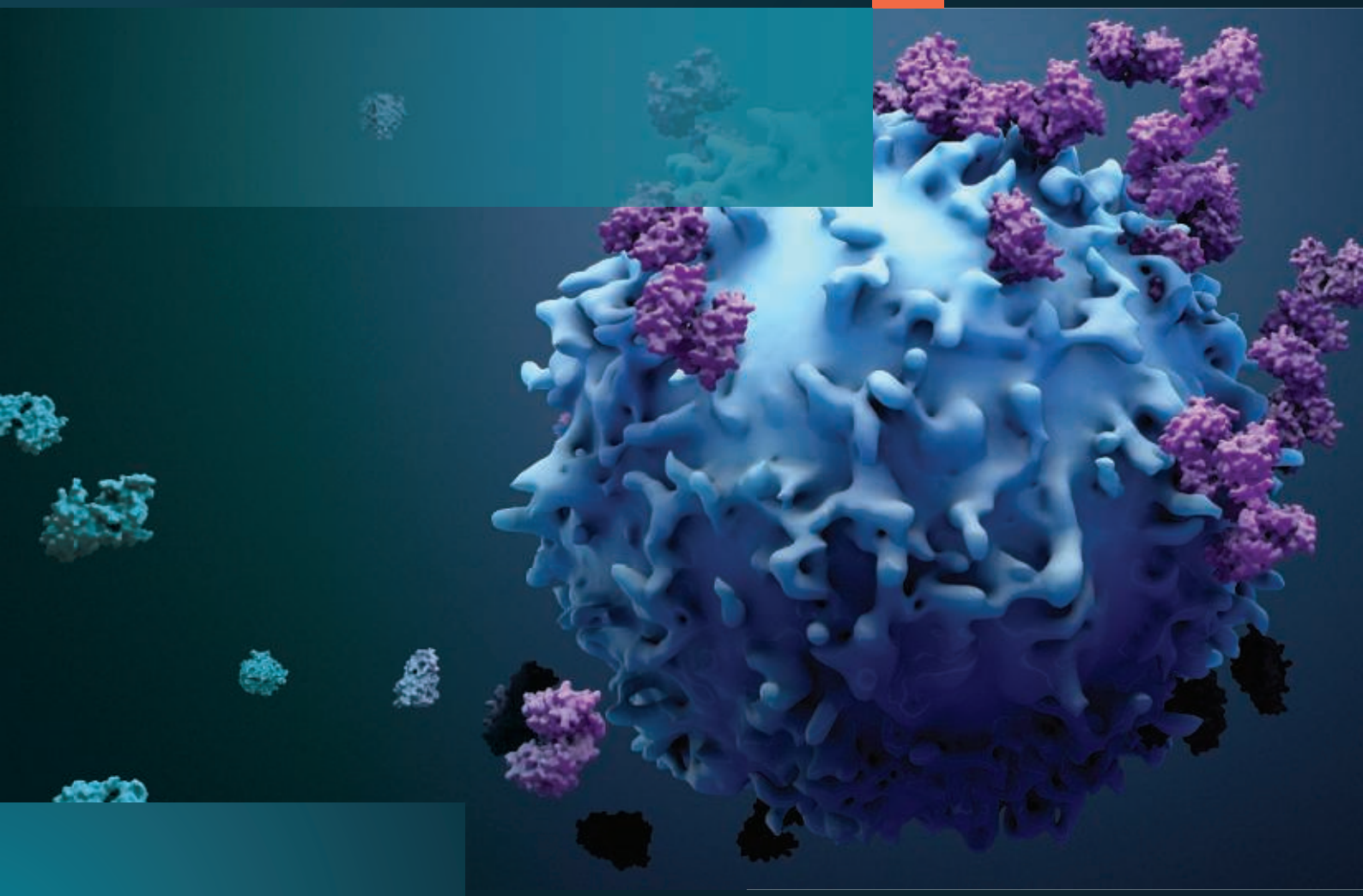
SIMBEC-ORION

Oncology Study Support

Delivering Oncology Studies for Over 25 Years



simbecorion.com

Bringing deep understanding

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

Our goal is the same as yours: to improve patients' lives. Patient recruitment and retention are key, and at the heart of this is our patient-centric approach. We understand that for some patients, the decision to participate in an early-stage clinical trial, especially in oncology, can be challenging. We strive for a personal approach to ensure patients feel supported and engaged throughout the study.

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.

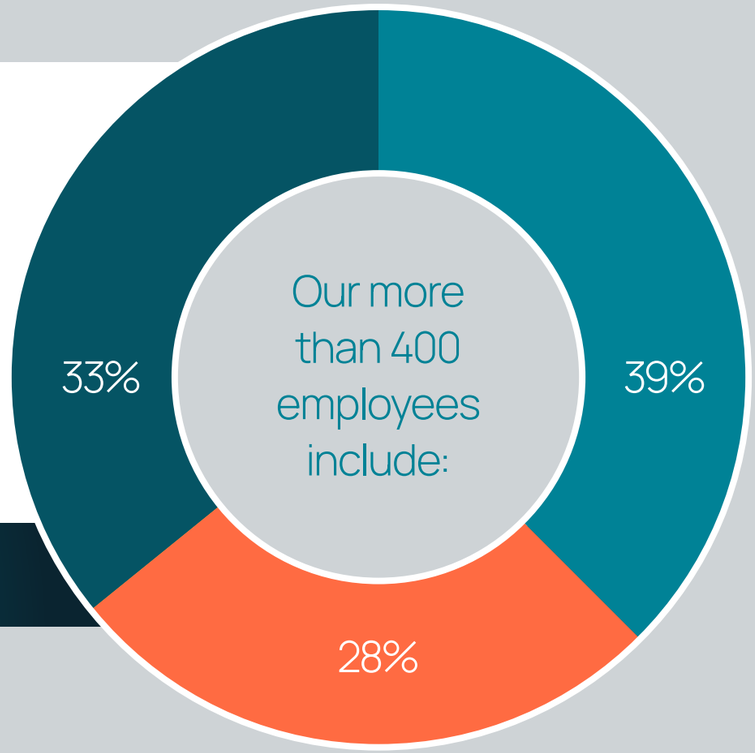
- Project Management
- Regulatory Affairs
- Consulting & Strategic Support
- Clinical Monitoring
- Central Laboratory
- IMP Management
- Medical & Pharmacovigilance
- Biometrics (Data Management & Statistics)
- Technical Writing
- PK/PD Studies
- Bioavailability & Bioequivalence Studies
- Bioanalytical Laboratory
- Scintigraphy
- Scientific Advisory Board (SAB)

An international, full-service clinical research organisation specialising in oncology studies

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

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 studies

The Simbec-Orion Scientific Advisory Board (SAB) is established to offer our clients additional support and guidance in our core therapeutic areas of oncology, including rare oncology.

The SAB consists of experts in their respective fields with extensive experience in:

- Clinical development
- Scientific consultancy
- Complex protocol design
- 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.

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.

Oncology drug development requires flexibility and determination at study sites with close study management guidance

We understand the importance of the right partnerships to ensure a seamless oncology study – not just with our clients, but with key reference oncology sites in Europe and the USA.

Simbec-Orion has established relationships with investigative sites and KOLs in oncology, which allows us to customise our approach and deliver both on your program and corporate objectives with expedited timelines. By keeping sites engaged throughout the study and providing tailored training and study support, we can ensure participating sites continue to stay motivated for the study duration. In addition, our Scientific Advisory Board is always on hand to support and has specialist experience in oncology.

We endeavour to provide a personal service for all our projects, offering bespoke solutions that are the right fit for our clients

Our size and low hierarchy management structure makes for agile, flexible processes – ideal for highly tailored, complex protocols and early-phase oncology studies. It allows us to rapidly respond to challenges or escalate issues quickly when required. Whether for issue escalation or advice mid-way through your project, our senior team is always on hand to offer support, because your success is our success.

Our teams are supported by best-in-class systems and our additional services ensure you have a robust supporting framework for your study.

We understand the complexities and challenges faced in oncology studies and have the right network to support your study

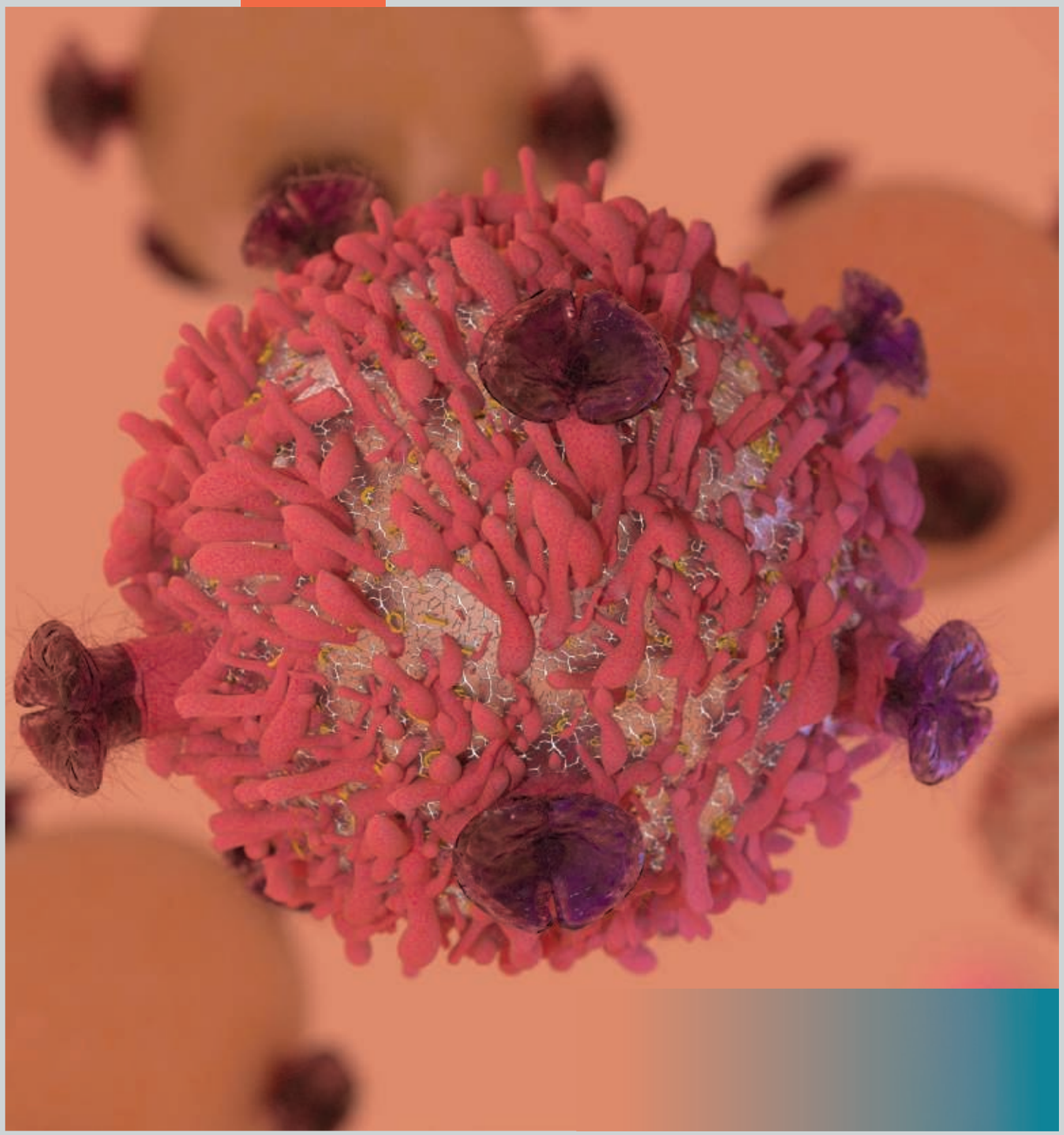
Experts in modular oncology trial design.

Experienced across multiple classes of product including: NCEs – small molecules and biologics, cell therapy, vaccines, antisense and gene therapy.

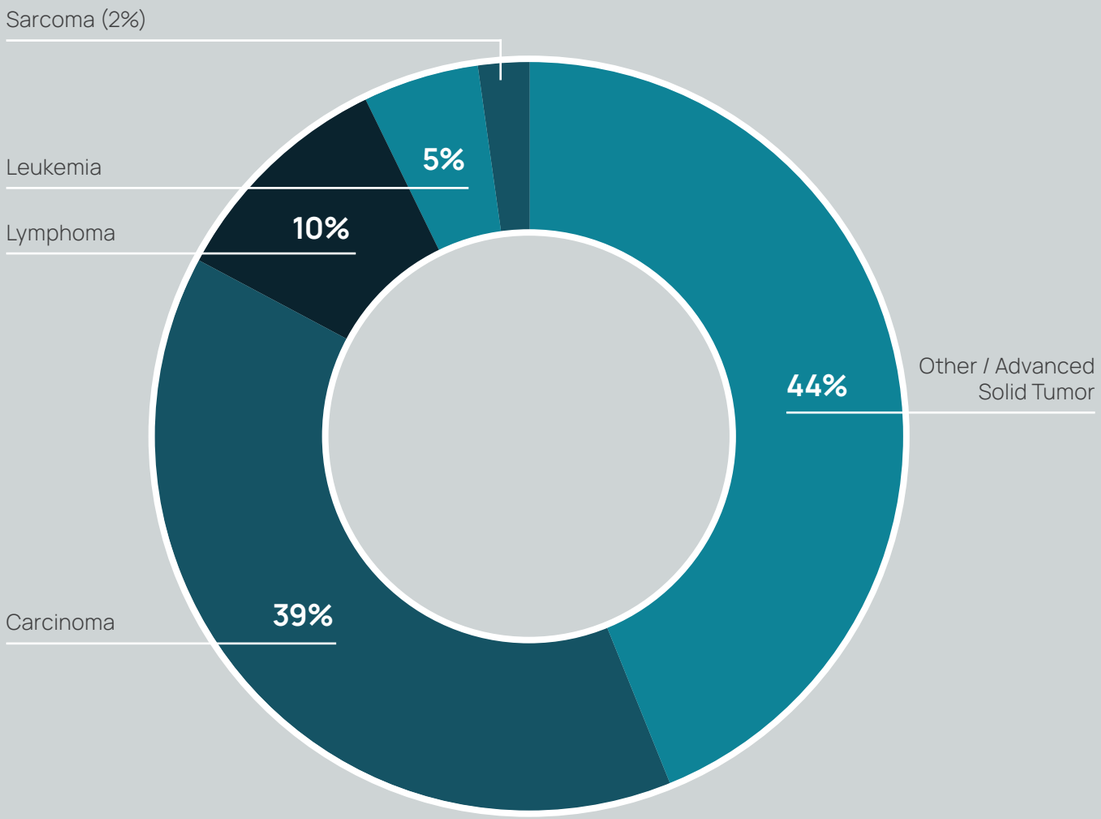
Supported by world renowned Scientific Advisory Board with oncology expertise.

As well as our established links with oncology centres across North America and Europe, our relationship with the Oncodistinct Network grants us access to additional cancer centres and university hospitals.

Established relationships with opinion-leading oncology clinicians, from both North America and Europe.

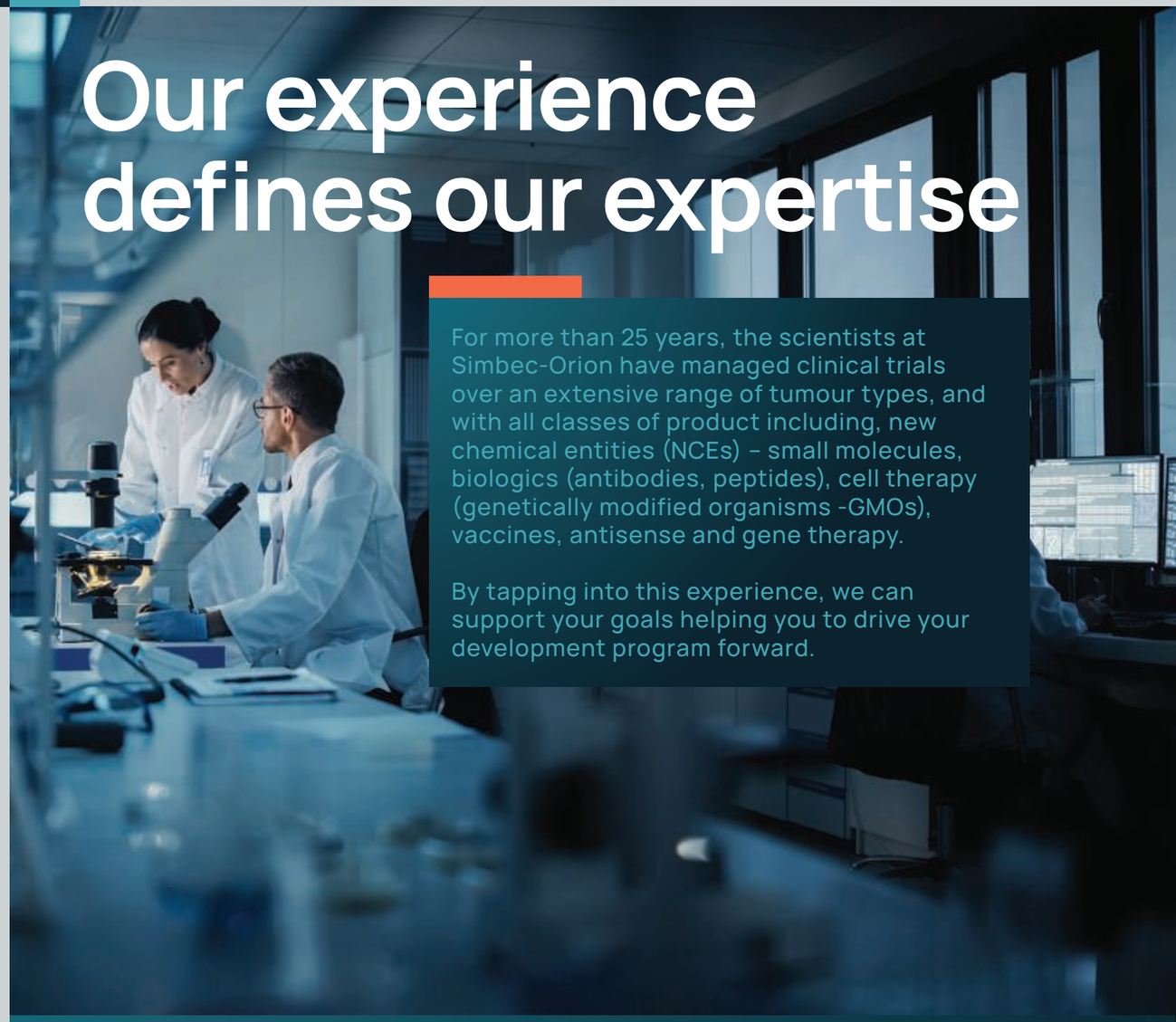


Percentage of studies by tumour type



As oncology experts, Simbec-Orion has vast oncology study experience across many tumour types, including rare cancers.

We hold specialist expertise in the rare oncology space with 25% of our rare disease experience in rare oncology indications.



Our experience defines our expertise

For more than 25 years, the scientists at Simbec-Orion have managed clinical trials over an extensive range of tumour types, and with all classes of product including, new chemical entities (NCEs) – small molecules, biologics (antibodies, peptides), cell therapy (genetically modified organisms -GMOs), vaccines, antisense and gene therapy.

By tapping into this experience, we can support your goals helping you to drive your development program forward.

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.

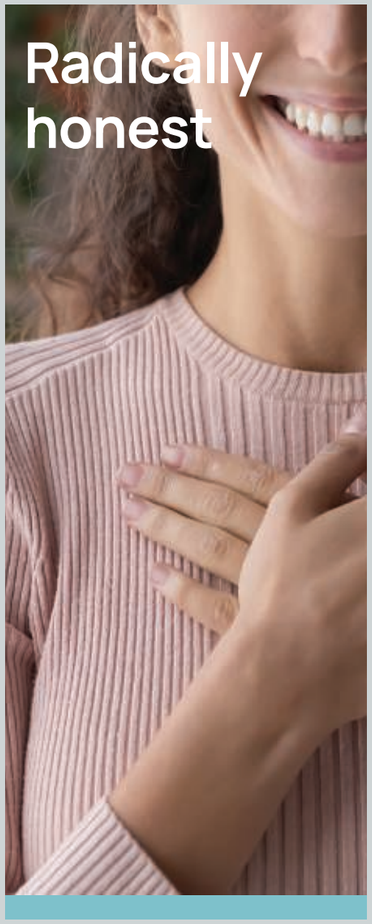
By attracting the right talent to join a team already proud to work for Simbec-Orion, we strive to continue to make a difference. Both to the way we work, and to the lives of the patients waiting for new and improved therapies around the world.

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.

Metastatic breast cancer

Phase III rescue study: resolving site issues through CRO collaboration and on-site training.

An open-label, randomized, parallel, two-arm, multicenter, international Phase III study in patients with recurrent or metastatic breast cancer previously treated with cytotoxic chemotherapy regimens.

A sponsor that had previously worked with Simbec-Orion invited us to re-monitor a percentage of work being conducted by a mega CRO on their phase III breast cancer study. The sponsor was questioning why they were not seeing a normal level of background noise in the study (particularly protocol deviations) and wanted us to help investigate.

Study objectives

- To review the active study sites and the monitoring practices and conduct of the existing CRAs.
- To identify any issues with the conduct of the study, including data collection and reporting, and report back to the sponsor.
- To work in partnership with the sponsor and existing CRO to rectify past issues and ensure the project remained within the inital projected timelines, and that high-quality, accurate data was obtained.

Challenges

Due to the size of the study, the sponsor wanted to continue the relationship with the mega CRO but wanted Simbec-Orion to work alongside them to resolve the issues identified.

This required a tactful approach which relied on honest communication and teamwork from all parties.

Our initial review confirmed that there were substantial issues with one of the sites, especially with the level of source data verification.

We were asked to examine more sites and review the RECIST assessment of tumours. We found that there were errors in the data collected, with potential problems across one-third of sites.

One site was highlighted by the sponsor as a potential fraud concern as data was constantly changing between visits.

Solution

A collaborative approach to CRA training and retrospective re-auditing of sites.

Senior, highly experienced CRAs worked alongside existing monitors

Our CRAs attended sites alongside the existing site monitors, resulting in re-monitoring extended in selected areas. Re-monitoring of tumour assessment data for a percentage of patients was requested and the highest recruiting site was judged to require 100% re-monitoring.

Dedicated time to develop a relationship and rapport across teams

We developed a mentoring strategy to train junior CRAs from the other CRO. Senior CRA's from Simbec-Orion shared guidance and experience, which was well received and improved performance.

Retrospective re-audit and re-SDV of all information from problem site

To accelerate timelines, we were able to organise the sample preparation under special conditions, precisely coordinating the time-critical delivery to our central laboratory.

Outcome

Simbec-Orion's high-quality monitoring by our experienced CRAs ensured that this large phase III study provided high quality, publishable data to support the further development of the drug.

Once additional attention was applied the study, it proceeded positively to completion and the sponsor was pleased with all parties' involvement.
Our collaborative approach and expertise helped the sponsor get the project back to original timelines, leading to a successful study after the rescue period, with all parties satisfied.

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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