CRO Charité Research Organisation

Scientifically driven

CRO Charité Research Organisation

We are an integrated contract research organisation and clinical site. We help our clients to move development projects from First Time in Human (FTIH) to Proof of Concept (PoC) as quickly and efficiently as possible.

Based in Berlin, at the very heart of Europe, Charité Research Organisation (CRO) was founded in collaboration with Charité – Universitätsmedizin Berlin.

The centrepiece of the CRO set-up is a state-of-the-art Phase I unit. This unit offers up to 90 in-patient beds, alongside a range of function and out-patient rooms. Additional out-patient facilities are utilised to support large scale screening activities and out-patient-only studies.

We undertake FTIH, multi-part adaptive design HV/patient and PoC studies. We also support the full range of Phase I study types, including bioavailability (BA), bioequivalence (BEQ), drug-drug interaction, food effect and thorough QT (TQT) studies. Our unit and dedicated screening facilities provide the optimal environment for the conduct of very large Phase I biosimilar studies and nutritional intervention trials.

We apply our scientifically driven approach to the full spectrum of development projects, including novel biologics, biosimilars, small molecules, medical devices, health technologies and nutritional products.

Scientifically driven

Charité Research Organisation

Welcome to the future of translational research and early clinical development

Ever since its foundation in 2005, CRO has contributed to the optimisation of translational research and the FTIH to PoC development process.

What sets CRO apart from other organisations is the ability to combine the best of both worlds – the scientific and clinical expertise of an academic centre with the operational excellence and recruitment capabilities of a dedicated contract research organisation.

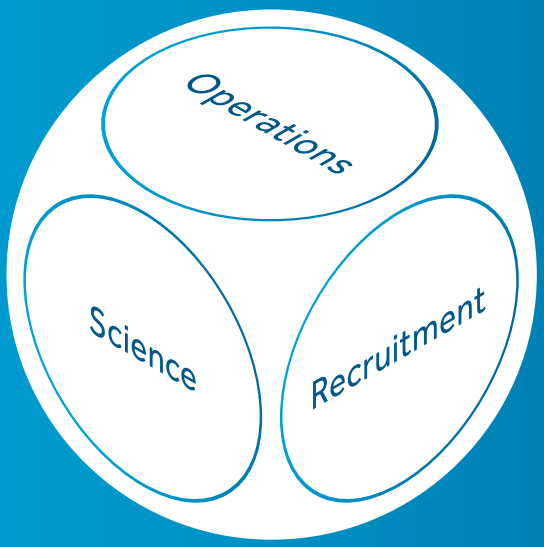
Multi-part adaptive design HV/patient studies and PoC studies are carefully planned by a dedicated Scientific Service team. While board certified physicians are at the core of CRO's experienced study team, an innovative recruitment approach assists with unrivalled enrolment rates.

CRO works closely with the clinics and institutes at the Charité. These partnerships allow us to seamlessly integrate specific therapeutic area expertise and capabilities into study conduct.

In this scientifically driven environment, CRO offers full service solutions for early clinical trials, tailored to the needs of each sponsor and each project individually – centred on the highest quality of clinical conduct.

Thanks to this operational set-up and world-leading patient and healthy volunteer recruitment capabilities, CRO delivers the best value solution for early clinical development.

We conduct your FTIH, Phase I and PoC studies



Scientific Expertise

In-house experience, collaboration with KOLs at the Charité

Operational Excellence

Customisable full service underpinned by excellence in clinical conduct

Recruitment Performance

Single-centre solutions thanks to world-leading recruitment rates

Value For You

Shorter timelines. Higher data quality. Lower overall cost.

Scientific Expertise

We are scientifically driven with access to multiple centres of excellence

Translational research and early clinical development require ever more effective engagement of clinical expertise, diagnostic technologies, biomarker analysis, and patients.

We offer extensive in-house expertise and a unique operational environment across the entire spectrum of medicine.

Our highly qualified and board certified study physicians take the lead in projects, typically assuming the PI function themselves.

By collaborating with leading clinics at the Charité and harnessing their capabilities and expertise, CRO implements complex clinical and biomarker assessments, while always retaining full operational control.

A perfect example is that of early studies in rheumatoid arthritis (RA), which require ever more subtle analysis. We investigate inflammatory biomarkers and measure subclinical synovitis by magnetic resonance imaging (MRI), ultrasonography (US) or near-infrared fluorescence optical imaging (FOI).

Scientific Expertise

Rheumatology Set-Up

Clinical Support

Prof. Dr. med. Gerd Burmester

Appropriate endpoint and inclusion criteria selection

Advanced Imaging

PD Dr. med. Kay-Geert Hermann

Demonstrate PoC using advanced imaging, such as MRI, US and FOI

Complex Biomarkers

Prof. Dr. med. Hans-Dieter Volk

ISO certified Immunological Study Laboratory (ISL)

Operational Excellence

Customisable full service underpinned by the highest quality clinical conduct

CRO offers a unique approach that combines the capabilities of a classical contract research organisation with those of a dedicated clinical site. This allows us to provide full service solutions tailored to the needs of each sponsor and each project individually.

We are uniquely placed to conceptualise, design, develop, implement and physically perform complex early clinical studies for you – and assist with assessing and interpreting the results.

While other contract research organisations are able to contribute with one or more of these functions, practically no one can truly see a project through from start to finish while maintaining direct control over the physical conduct of the study.

It would be one thing if we were able to do this with respect to healthy volunteer studies only. The fact that we can deliver the same service for early clinical studies in patients is what sets us apart.

We are able to provide a genuine alternative to the current model in which a contract research organisation implements and manages a study, while relying on the physical conduct being performed by others. Our approach, which sees the study managed and conducted in-house, delivers higher data quality, allows for more complex assessments to be included, and ultimately saves time and reduces overall cost.

Operational Excellence

Study Concept	Study Design	Study Conduct	Study Results
Study conceptualisation, endpoint definition, regulatory consultancy	Protocol development, combined models, PK & PD strategy	CRO Phase I unit, biomarkers and imaging, collaboration with Charité	Clinical data assessment, support for go/no-go decision making

Recruitment Performance

World-leading patient and healthy volunteer recruitment performance

Subject recruitment is at the forefront of all that CRO does well. Without successful recruitment, no level of operational and scientific excellence would allow us to make a fundamental difference and deliver outstanding value.

We have the ability to enrol both healthy volunteers and patients at an order of magnitude higher than what is conventionally thought realistic. Access to a large database and direct-to-patient marketing facilitate unrivalled recruitment across a wide spectrum of indications.

German-wide recruitment and pre-studies to identify potentially eligible patients help accelerate recruitment for rare populations.

Excellent recruitment rates in combination with our clinical expertise and ability to harness diagnostic technologies and biomarker capabilities allow us to implement truly unique projects for you.

We offer single-centre solutions for a wide range of therapeutic areas and study types, including PoC and biosimilar studies.

Recruitment Performance

Feasibility Assessment

Analysis of study population and inclusion criteria, estimation of viable monthly recruitment rates

Direct-To-Patient Marketing

Development and implementation of study-specific marketing strategies and patient communication

Information & Screening

Dedicated facility for information sessions, consent process and screening activities

Value For You

Delivering the best value solution for early clinical development

Value can only be assessed by looking at the whole picture and the quality that any given solution delivers. CRO combines scientific expertise, operational excellence and unrivalled recruitment performance to provide ultimate value for money.

We do this by delivering on three main fronts. First, we provide a solution for early clinical studies that reduces the number of sites and providers required. In this model we act as both the contract research organisation and the investigational site. That directly reduces project complexity and overall cost.

Secondly, through this approach, we save you time in the set-up phase and right through to completion of the clinical conduct phase. Thirdly, our ability to enrol large numbers of subjects in a controlled single-centre environment results in higher data quality and allows for more meaningful and less complicated integration of sensitive imaging, diagnostics and complex biomarkers. These three benefits combine to deliver the best possible overall value and unrivalled handling of complicated trials.

Value For You

Shorter Timelines

We are world-leaders in patient recruitment and multi-part adaptive design HV/patient studies.

Your product benefits from a faster PoC.

Higher Data Quality

We utilise a standardised, single-centre environment, including local imaging and biomarker analysis.

Your study benefits from excellent data quality.

Lower Overall Cost

We minimise the number of providers and clinical sites required, reducing complexity and operational costs.

You benefit from a significantly lower overall cost.

Get in Touch

Discuss your early clinical trials with us

Charité Research Organisation GmbH
Charitéplatz 1
10117 Berlin, Germany

+49 30 450 539 211
enquiries@charite-research.org
www.charite-research.org

Send An Email

Visit Our Website

www.charite-research.org