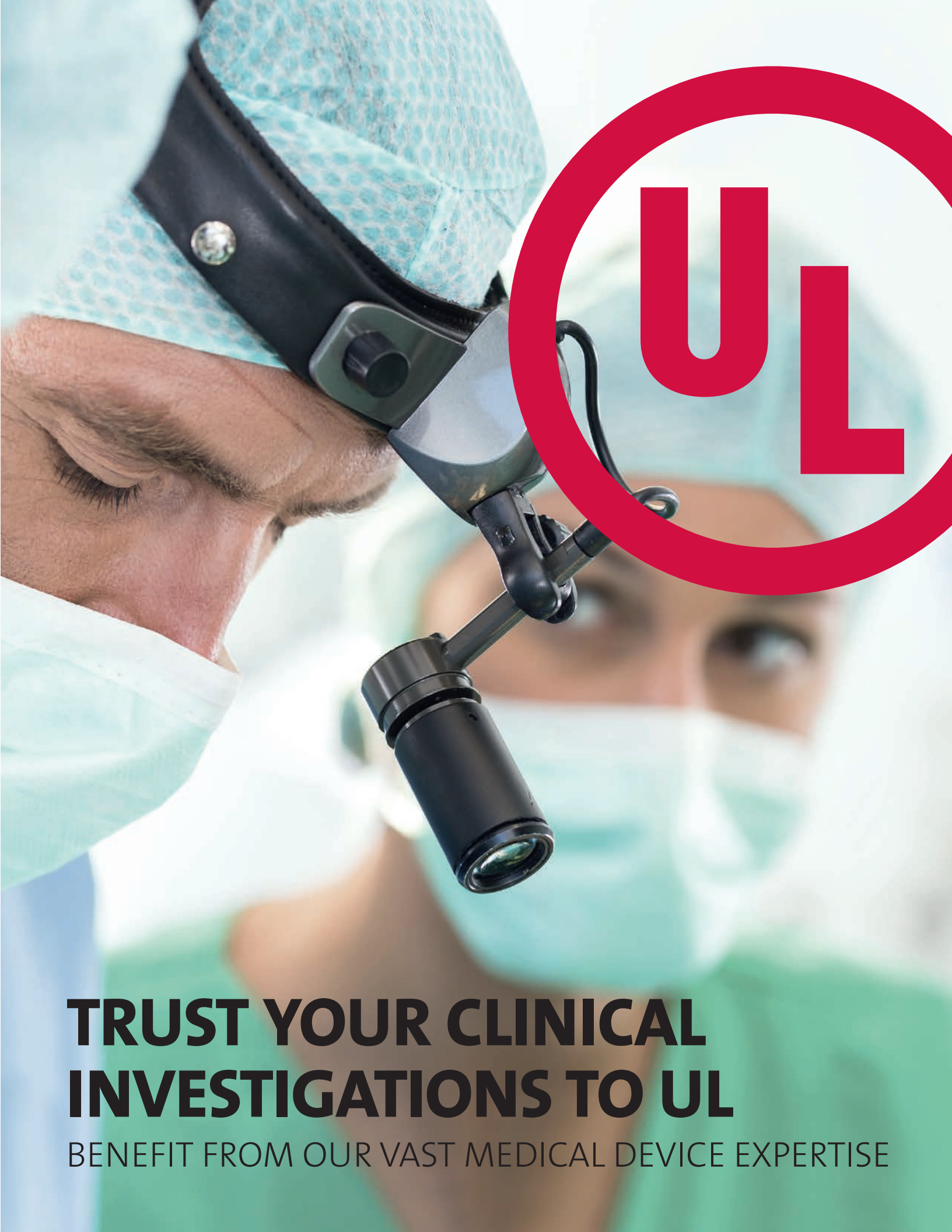


TRUST YOUR CLINICAL INVESTIGATIONS TO UL

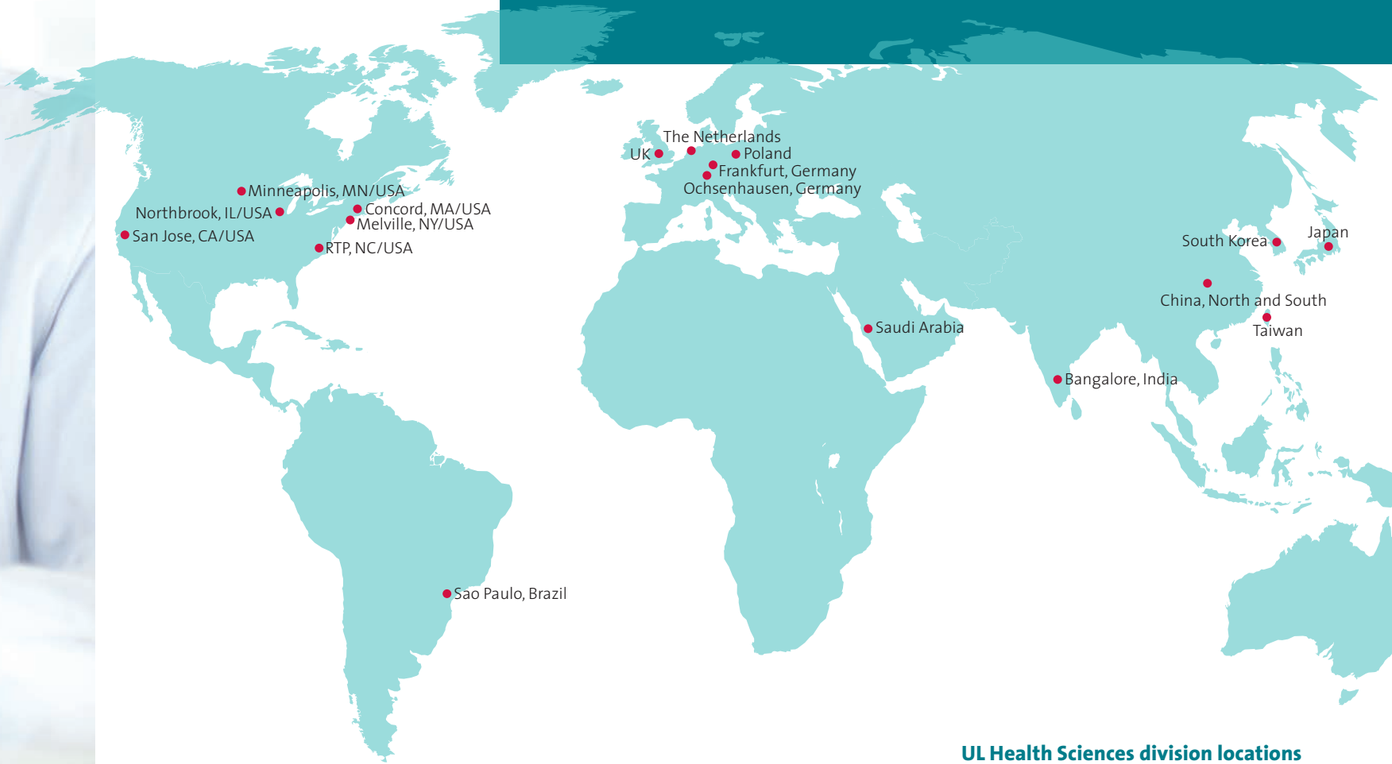
BENEFIT FROM OUR VAST MEDICAL DEVICE EXPERTISE

Our experienced medical device-focused clinical research team helps your study stay on track

With a specialized focus and expertise in the medical device market, the UL Contract Research Organization (CRO) group has more than 17 years of experience in various therapeutic areas in the clinical setting.

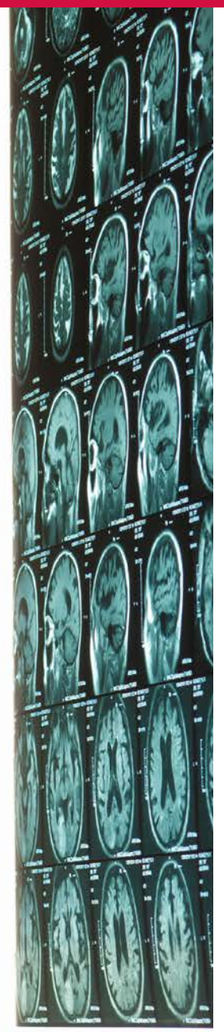
Our qualified team, globally headquartered in Germany, helps you activate sites in many countries, helps ensure patient safety and collects high quality clinical data. We do so efficiently – so if you want to market and sell your products in multiple markets, we can help design the studies to accommodate different regulatory schemes.

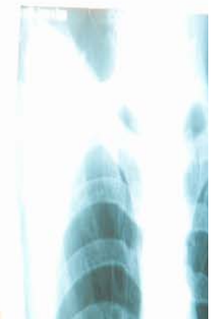
We have helped both large and small companies successfully complete clinical investigations at many sites in several countries. We know the time and effort it takes to conduct a successful clinical investigation. This relationship is more than a project – we will be part of your team, by your side throughout the entire process.



UL Health Sciences division locations

Work with UL for your clinical trials





UL is a premier global independent safety science company that has championed progress for more than 120 years. With nearly 11,000 professionals, guided by the UL mission to promote safe working and living environments for all people, UL uses research and standards to continually advance and meet ever-evolving safety needs. Our Life & Health business provides comprehensive services, including CRO, to support medical manufacturers with global regulatory approvals.

- **Global reach**
  Our CRO team has direct contacts in several study sites around the world. Our team members speak several languages which helps build relationships, trust and enhances communications.

- **Local anchoring**
  Our CRO staff is located in multiple countries, minimizing travel costs for on-site activities and allowing the local site to interact with the team member in the local time zone and language. In addition, UL has offices around the world that can augment the CRO services with additional support as needed.

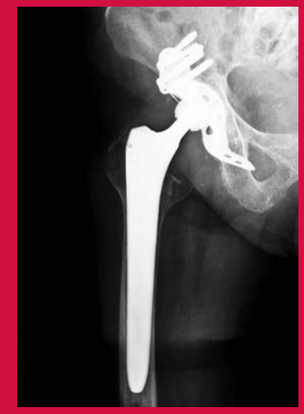
- **Flexibility**
  Our team is fully prepared to take on one or more tasks related to making your clinical investigation a success. We can be an extension of your staff so you can focus on other business needs.

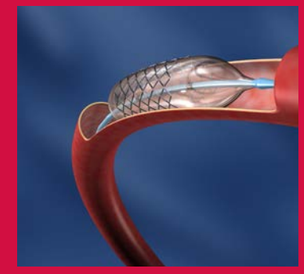
- **Focus**
  Our team is dedicated to serving medical device companies and supporting the unique needs of the medical device clinical investigations and regulatory nuances. Having this focus has allowed our team to gain specific experience and knowledge in several therapeutic areas.

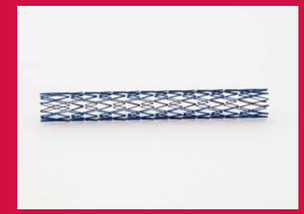
- **Dedicated Project Management**
  Each clinical project has its own project manager, specifically experienced in the therapeutic area and discipline.

- **Customer Service**
  We know the clinical investigations are extremely important to you, your employees and your business. Our team will work with you closely every step of the way.

- **Market Entry Alignment**
  Since the EU tends to be the first location devices are launched, working with a team based in Germany, the largest EU country for medical devices is the logical choice for your clinical investigation.







Support for your unique study needs relationships

EXPERTISE

Our team has extensive experience in many therapeutic areas, including:

- Cardiovascular
- Dermatology
- Ear Nose Throat
- Gastroenterology
- Gynecology
- Hematology
- Metabolic diseases
- Neurology and Neurovascular
- Ophthalmology
- Orthopedic and Spine
- Plastic Surgery
- Pulmonology
- Urology
- Vascular diseases

Our medical experts also have experience and knowledge in other therapeutic areas and we can reach into the UL family of companies for specific expertise as needed. Just ask us.

SERVICES

UL can be your clinical partner for the entire project or one or more areas of support:

☑ Study Design

The study design sets the stage for the rest of the investigation and can be one of the most important parts of the process. Our team has designed both relatively simple and complex studies to meet a variety of needs, including market approval, feasibility, pilot/pivotal and more.

☑ Study Management / Monitoring

Our seasoned and knowledgeable clinical project managers work closely with our clinical monitors (CRAs) and sponsors to coordinate all study activities and help ensure your project is on schedule and on budget. We actively monitor the timelines and the compliance of the regulatory and normative provisions within the planned budget. Our CRAs are on-site regularly and also verify that your clinical investigation is conducted in compliance with the provisions of the clinical investigation plan (GCP), ISO 14155 and the Declaration of Helsinki.

☑ Medical writing

Our team is skilled and experienced in preparing the essential documents you need for the success of your clinical investigation. We can prepare your investigator's brochure, clinical investigation plan, patient information & informed consent, the final clinical report and other documentation.

☑ Regulatory submissions

Our team has extensive knowledge in the evolving regulatory requirements for many countries. Our regulatory affairs specialists help ensure that the various national and international regulations involved in the conduct of your clinical investigations are met.

☑ Legal Representation

The EU Clinical Trial Directive 2001/20/EC requires every sponsor to have an in country representative. If your team is based outside of the country where your clinical investigation is taking place, UL's local team can be the official in country representative.

☑ Data Management

Depending on your needs and those of the regulatory bodies, we offer the classic paper-based Case Report Form (CRF) as well as an electronic form which complies with international standards (e.g., 21 CFR part 11). In advance of the statistical evaluation, the completeness and validity of your clinical data are verified and changed if necessary (query process and data cleaning).

☑ Biostatistics

Our statisticians are involved in your project at a very early phase to develop a suitable study design and determine the proper evaluation methods. The analysis of the acquired data is performed by experienced statisticians with validated statistics software.

☑ Safety Management

Clinical Safety Management is an important aspect of any study. Our team can support the reporting and administrative work associated with adverse events (AE), clinical events committees (CECs) and data safety monitoring boards (DSMB).

☑ Medical Regulatory Advisory Services

UL's regulatory technical consultants provide the support needed to help you and your organization understand each country's unique requirements and receive global regulatory approvals for your medical and IVD devices. This support includes aspects of clinical, non-clinical, technical file submission, quality system inspections, radiation registration, FDA remediation, risk management and the steps involved to submit registrations.

☑ Training and Seminars

We are happy to share our experiences in clinical testing with our customers. We offer seminars, public and private training, and advisory services. Invitations to our seminars and registration forms are available for download on our website www.ul-mdt.com.

STUDY TYPES

Depending on your needs, we can conduct various types of clinical studies:

- Market-approval
- Feasibility
- Pilot
- Pivotal
- Post-Market
- Registry
- Reimbursement

EUROPE

Denmark
T: +45.44.85.65.65
E: CustomerService.dk@ul.com

France
T: +33.1.60.19.88.00
E: CustomerService.fr@ul.com

Germany
T: +49.69.489810.0
E: CustomerService.de@ul.com

UL TTC
T: +49.2151.5370.370
E: ttc@ul.com

Italy
T: +39.02.92.52.65.00
E: CustomerService.it@ul.com

Poland
T: +48.22.336.33.00
E: info.pl@ul.com

Spain
T: +34.93.368.13.00
E: CustomerService.es@ul.com

Sweden
T: +46.8.795.4370
E: CustomerService.se@ul.com

The Netherlands
T: +31.26.376.4800
E: CustomerService.nl@ul.com

United Kingdom
T: +44.1483.302.130
E: CustomerService.uk@ul.com

AMERICAS

Argentina
T: +54.11.4316.8210
E: CustomerService.ar@ar.ul.com

Brazil
T: +55.11.3049.8300
E: info.br@ul.com

Canada
T: +1.866.937.3ULC, 1.866.937.3852
E: customerservice@ulc.ca

Mexico
T: +52.55.3000.5400
E: CustomerService.mx@mx.ul.com

United States
T: 877.UL.HELPS, 1.877.854.3577
E : cec@ul.com

ASIA PACIFIC

Australia
T: +64.9.415.3355
E: customerservice.anz@ul.com

China
E: customerservice.cn@ul.com

Beijing
T: +86.10. 5977.2006

Guangzhou
T: +86.20.3213.1000

Shanghai
T: +86.21.6137.6300

Suzhou
T: +86.512.6808.6400

Hong Kong
T: +852.2276.9898
E: customerservice.hk@ul.com

India
T: +91.80.4138.4400
E: customerservice.in@ul.com

Japan
E: customerservice.jp@ul.com

Ise
T: +81.596.24.6735

Tokyo
T:+81.3.5293.6200

Korea
T: +82.2.2009.9000
E: customerservice.kr@ul.com

Malaysia
T: +603.5632.5922
E: sales.sg@ul.com

New Zealand
T: +64.9.415.3355
E: customerservice.anz@ul.com

Singapore
T: +65.6274.0702
E: sales.sg@ul.com

Taiwan
T: +886.2.7737.3168
E: customerservice.tw@ul.com

Thailand
T: +66.2.207.2408
E: customerservice.th@ul.com

For more information on
UL's Clinical Investigation Services (CRO)
visit **ul-mdt.com**
call **1-888-503-5537** (US) or **+49 7352 9114.0** (EU)
email **Medical.Inquiry@ul.com**

artemis 9/2015