06.

Training

SCRC is the exclusive partner of ACRP (Association of Clinical Research Professionals) in mainland China. Through cooperation with international partners such as ACRP, we provide a series of certified training programs, education, certification and exhibition services to clinical research professionals. We aim at establishing a platform of local, regional and international clinical training activities and works as a bridge to link pharmaceutical industry, academy and government.

Bio-bank

SCRC provides tissue, blood and urine sample collection, storage and analytical services in accordance with the ICH-GCP and ethics guidelines. These specimens will form a foundation of a bio-bank with an ultimate goal of facilitating translational medicine research and leverage the research power by bridging clinical practices and basic research.

Quality Assurance

SCRC has an independent QA group reporting to the CEO that conducts ongoing quality and compliance assessments of all the services we offer. The QA group regularly conducts internal system audits to ensure compliance with GCPs, SOPs, vendor qualifications and commitments to our clients. The internal audit program is an integral part of SCRC's continuous improvement program. The audit activities include:

- Clinical site audit
- Vendor audit
- Internal system/process audit
- Audit of database and statistical tables
- Clinical study reports
- Hosts client audits

SCRC's quality control, quality assurance and auditing activities ensure a delivery of the highest quality services to our clients.

www.scrcnet.org

Focus on Qualities,
Focus on Customers

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上海医药临床研究中心
SHANGHAI CLINICAL RESEARCH CENTER

About us...

About us

Shanghai Clinical Research Center (SCRC) operates as a 3rd-party full-service assessment and resource center to facilitate drug development. SCRC is developing a core resource platform with coverage of clinical research sites throughout China. A fully equipped central laboratory with GLP capabilities, a state-of-the-art data management and a bio-statistics system position SCRC as a leader in drug development services in China.

Founded under the collaborative framework of the Ministry of Science and Technology and the Shanghai Municipality in 2008, SCRC endeavors to be a pioneer in the globalization of drug development in China by provision of the link necessary between pharmaceutical companies and hospitals. With superior technical skills, abundant public resources, necessary infrastructure and a network providing access to large patient populations, SCRC is dedicated to meeting the challenging needs for clinical expertise,quality services and technological innovation in global drug development.

VISION

To become a world-renowned clinical research center by providing full-service clinical trial capabilities that comply with international standards.

MISSION

To be the vanguard for the globalization of clinical research in China

To be the advocate of the national innovation strategy for clinical research on new drugs

To be the propeller of the healthcare industry development in China

01.

02.

Clinical Research Management

SCRC has created a one-stop customized service package that has capabilities for phase I to phase IV clinical trials. Our comprehensive range of services covers the full spectrum of clinical development in compliance with ICH-GCP and Chinese GCP. We have a distinguished team of experienced professionals who bring an in-depth expertise from industry, research institutes and hospitals. We know what it takes to bring your new product to the market efficiently and cost-effectively.

SERVICES

Regulatory Affairs

- Consultation on strategic, regulatory, scientific and safety aspects of clinical development in China
- IND, NDA and import license applications
- Strategic regulatory advice and drug development plans for the Chinese market
- Liaison with regulatory authorities
- Professional preparation of medical reports, summaries, and other productinformation
- Expertise in global regulatory affairs

Phase I-IIa Studies

- Safety and dose escalation studies
- Pharmacokinetics/pharmacodynamics studies
- Bioavailability/bioequivalence studies
- Pharmacogenomics studies
- Ethnic sensitivity evaluation
- Age, gender and food effect as well as drug interaction studies
- Hepatic and renal insufficiency studies

Phase IIb-IIIa Studies

- Hospital network for oncology, CVS, CNS, Endocrinology
- Project management
- Scientific protocol writing
- Active participation in follow-up monitoring to support long-term retention
- Flexible resourcing for evolving project needs

Phase IIIb and IV Studies

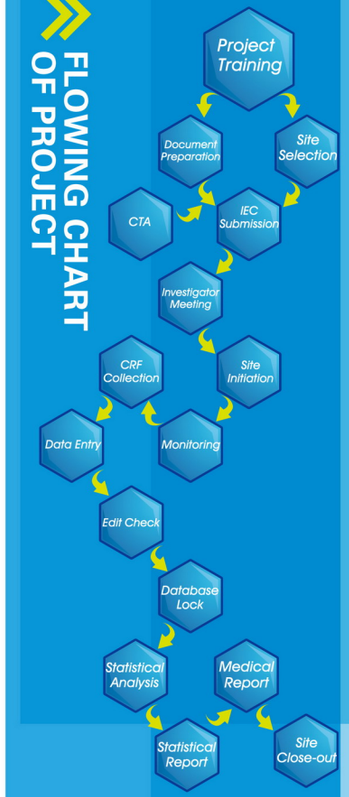
- Post-marketing study design
- Post-marketing research training

Phase I Clinical Research Unit

Shanghai Clinical Research Center Phase I Clinical Research Unit (SCRC-PCRU) is one of the leading organizations involved in phase I clinical trials in China. SCRC-PCRU was previously known as Xuhui Central Hospital Phase I Clinical Research Unit. It has a long history of working with the pharmaceutical industry to offer special expertise in conducting early phase clinical studies under SFDA and FDA IND applications for innovative products. Since 1999, the unit has been engaged in numerous phase I clinical trials, bioequivalence studies and clinical pharmacology studies. The unit operates in accordance with ICH-GCP and Chinese GCP. All staff at SCRC-PCRU are GCP trained, and its investigators are certified by Association of Clinical Research Professionals (ACRP), USA.

03.

FLOWING CHART OF PROJECT



DM & Biostatistics

In compliance with ICH-GCP and in accordance with US FDA 21 CFR Part 11 regulations concerning the DM system, our data management and biostatistics services are tailored to fit your clinical trial needs. We employ advanced technologies, optimized processes and professional teams to meet specific requirements of each project. The excellent planning and abundant resources can ensure high quality data with strict timelines and budget constraints.

Data Management

- CRF design and review
- Data preparation and entry
- Database setup
- Medical coding
- Double data entry or EDC
- Data validation and edit check
- Data lock
- Database quality control
- Blind data review

Biostatistics

- Statistical design
- Sample size estimation
- Randomization schedule
- Drug repackage management
- Statistical analysis plan development
- SAS programming
- Statistical analysis
- Statistical analysis report writing
- Clinical study report writing

We have designed and implemented an effective quality control system to ensure each step is done in accordance with the high standards of our procedures.

Shanghai Clinical Research Center

04.

Independent Ethics Committee

The Independent Ethics Committee (IEC) at SCRC was established in October 2008 in compliance with the "Operational Guidelines for Ethics Committees that Review Biomedical Research" proposed by the World Health Organization (WHO), the "Universal Declaration on Bioethics and Human Rights" by the United Nations Educational, Scientific and Cultural Organization (UNESCO), the "Ethical review of biomedical research involving human subjects" by China's Ministry of Health, the ICH GCP and the Chinese GCP. It operates according to a set of written Standard Operating Procedures, with full respect to science and human rights. The IEC is responsible for the review of clinical research conducted in Shanghai and across China. The IEC abides by the constitution and the laws that pertain to research conduct.

The Committee is an independent body consisting of specialists in ethics, medical research, clinical practice, law and lay representatives, and is chaired by Dr. Ching-Li Hu, member of the UNESCO International Bioethics Committee, former Assistant Director-General of WHO, and member of the Ethics Committee, Ministry of Health.

Mission

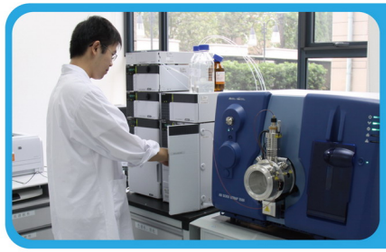
To provide protection for the rights and welfare of human subjects participating in the research through the initial and ongoing review of clinical research.

Function

With the principle of fairness, independence, diversity, transparency and non-profit, the Shanghai Clinical Research Center Independent Ethics Committee is set up to provide the following services:

1. Independent ethics review
2. Patient oversight for safety
3. International cooperation and exchanges
4. Ethic related education and training

05.



Central Lab

In compliance with ISO15189 and CAP, the central laboratory offers comprehensive and flexible services, including clinical laboratory testing services, drug evaluation services and laboratory technology validation services. With more than 1500 square meters of laboratory space, the central laboratory is accommodated with state-of-the-art technologies designed to work with our clients to achieve their testing protocol needs.

Services

Clinical Laboratory Testing

The Clinical Laboratory Testing Division has 8 laboratories, fully equipped with advanced equipment and instruments:
Clinical Immunology Lab, Clinical Biochemistry Lab, Clinical Microbiology Lab, Clinical Molecular Biology Lab, Clinical Hematology and Urinalysis Lab, Flow Cytometry Lab, Element Analysis Lab and Cytogenetics Lab.

Pathology

The Clinical Pathology Lab offers testing in anatomic pathology, cytopathology and molecular pathology for pharmaceutical companies and medical institutions.

Analytical Chemistry

The Analytical Chemistry Division has a pharmacokinetics/ pharmacodynamics laboratory, which has access to LC-MS/MS technologies, etc. It can carry out formulation analysis, phamacokinetics assessment and other chemistry analysis services as needed.

Quality Assurance

The central laboratory has a dedicated quality assurance team to ensure that all the laboratory services are conducted to meet high quality standards .