Contribution to Healthy and Prosperous Society Creation through Comprehensive Support to Pharmaceutical R&D

Driven by a strong sense of mission for the contribution to the quality of life and health,

we, SRL Medisearch, have achieved remarkable growth and solid performance. We have always contributed and will do our best to support the pharmaceutical R&D of the customers,

rendering high quality services with the forefront of analytical technologies and preciseness at the peripheral services.



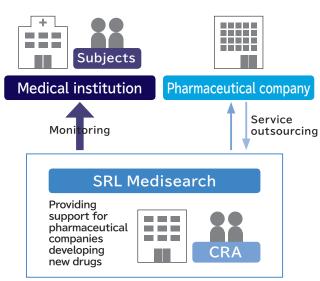
CRO Services

Monitoring Services to Ensure Data Accuracy and Quality

We use our expertise and fields of specialty to help our clients obtain manufacturing approval.

Monitoring Services

Here at SRL Medisearch, we provide reliable, quality monitoring services in line with Good Clinical Practice(GCP), with the aim of bridging the gap between pharmaceutical companies and medical institutions so that safe and effective new drugs can be put to good use in a clinical setting as soon as possible. One of the key factors for success with clinical trials depends on selecting the right investigator's site and principle investigator. By harnessing the wealth of information, experience and expertise that the Miraca Group has built up through clinical testing in the medical sector, we are able to quickly and reliably implement projects, including proposals for investigator's sites, in our capacity as an outsourcer.



QC Services

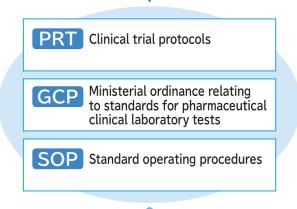
Quality control (QC) is a service designed to ensure that clinical trials are conducted in line with GCP and clinical trial protocols, and that they are adequately monitored. Services include inspecting documents prepared by Clinical Research Associates (CRA), trial-related documents submitted to or obtained by medical institutions, and the

contents of records, as well as checking to make sure that monitoring has been carried out at the correct time and via the correct methods. In addition to being an important process in terms of effectively moving projects forward, QC also helps to enhance monitoring skills, by providing feedback to CRA on items picked up during checks by QC staff so that they can make the necessary improvements. Here at SRL Medisearch, we provide high quality clinical trial data throughout our QC services.

Our Experience

•Fields of Specialty
Chronic pain fields
Neuropathic pain
Peripheral neuropathic pain
Central neuropathic pain
Infectious disease fields (MRSA/community-acquired pneumonia)
Dermatological fields (shingles/herpes)
Hepatitis fields (hepatitis C/cirrhosis)

Reliable and Fast Project Implementation



Quality Control

- ·Checking trial-related documents
- ·Carrying out process checks
- Storing and managing trial-related documents
- Ensuring consistency across prepared documents
- ·Providing guidance for monitors
- •Far-Ranging Experience
 Global clinical trial experience
 Support for English EDC systems
 e-Pro support
 Direct support for CCR excite ins

Direct support for GCP onsite inspections and document-based conformity inspections

Support for various monitoring tools

Experience in running various forms of advertising, including newspaper ads

Quality Management Systems and Human Resource Development

Systematically improving and developing to ensure customer satisfaction

Quality Management Systems

Our aim is to continue providing high quality services and accurate clinical data, so that we can maintain the trust and satisfaction of all of our customers conducting clinical trials. To achieve that, each and every one of employees is motivated by a strong sense of duty and self-awareness of the need to protect life and people's health. As well as going about our duties on a daily basis, we also carry out ongoing quality improvement activities based on our quality management systems (QMS).

Quality Policy

Our employees strive to make ongoing improvements in line with our QMS and provide high quality products and services to guarantee Customer's satisfaction, based on the principle that the Customer always comes first.



Human Resource Development

Basic policy on human resource development

To grow up continuously toward time to come, SRL Medisearch regards "human resource development" as a primary importance management subject. We plan and carry out various educational training programs for raising human resources with a high sense of ethics and the speciality to work widely.

Leadership	We develop education and training programs designed to energize individuals and the organization as a whole, taking into account essential skills and abilities that employees need to master, as well as leadership. We also provide support for employee career development.
Professional development	We are constantly improving specialist training in line with departmental business plans and standard operating procedures (SOP), in an effort to develop professional human resources.
Improving quality and services	We carry out human resource development with the aim of sharing the values set out in our QMS between all employees, based on an understanding that everything depends on the quality of our products and services.

Privacy Policy

We, SRL Medisearch Inc. believes it is its social responsibility to handle personal information including specific personal information properly under the Privacy Policy given below.

We intend to do our best to protect such information by improving the system and management method for the protection of personal information.

1. Observance of laws and regulations

We comply with laws, regulations, and executive order regarding the proper handling of personal information including the Act on the Protection of Personal Information and the Act on the Use of Numbers to Identify a Specific Individual in the Administrative Procedure.

2. Proper handling of personal information

We specify the purpose of use to collect, use, disclose personal information in a proper and fair manner within the limits of necessity in connection with the execution of our services.

We handle personal information to be collected within the scope of purpose of use and take measures to prevent any such information from being used for any other purpose.

3. Safety measures

Our policy is to take preventive measures against the forecasted hazard to which the personal information is exposed, such as illegal access, loss, destruction, alteration and leakage and to take suitable countermeasures should an incident or accident occur.

4. Request for disclose and complaints handling We faithfully and swiftly correct, add, delete or suspend corresponding information based on verification of the request.

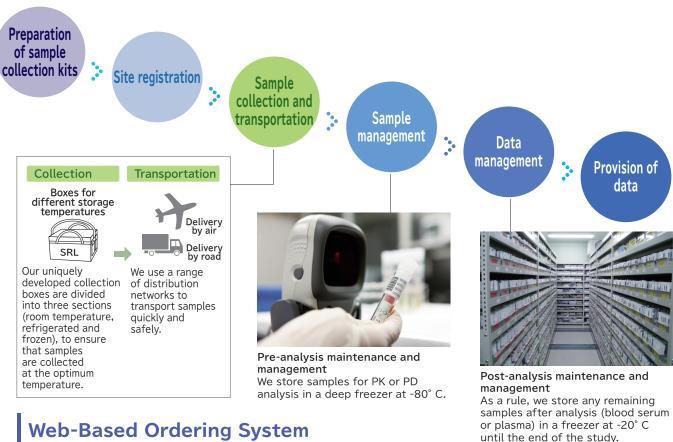
Kaoru Nakajima President & CEO SRL Medisearch Inc.

Clinical Study Support

Full Support, from Preparing Sample Collection Kits to Coordinating Operations

Establishing the best partnership to meet our customers' varying needs

Clinical laboratory tests are essential to all companies and organizations conducting clinical trials. As professionals in handling clinical laboratory test data, we specialize in clinical trials here at SRL Medisearch and offer support for customers engaging in harmaceutical R&D.In the field of new drug development, driven by the need to provide highly effective and safe pharmaceuticals of the highest quality as quickly as possible, we provide cutting-edge analysis technology and precise, high quality services. Combining advanced technologies, a wealth of expertise, an extensive distribution network and effective IT solutions, we aim to establish the best partnership possible with our customers and investigator's site, as part of our comprehensive support services for pharmaceutical R&D.



Orders for sample collection kits, setup, and sample collections can all be requested online. Our web-based ordering system is accessible from anywhere at any time, and even allows customers to check the status of their orders.



Comprehensive Support Underpinned by the Latest Technology

Precisely catering to customers' needs as a leading company

Central Laboratory for Clinical Trials

At our central laboratory, we carry out the safety testing and PK/ADA analyses essential to clinical trials. We are ISO-15189- and CAP-certified, and operate as a Good Laboratory Practice (GLP) facility.

Support for Molecular-Targeted Drug Development (Biomarker Screening)

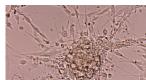
We conduct a wide range of tests integral to today's precision medicine, including genetic tests (NGS/qPCR), IHC staining, and FISH testing.

Biological Safety Testing (Quality Testing)

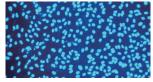
We carry out various quality tests set forth by the ICH for biopharmaceuticals and cell/tissueengineered medical products using biological techniques.

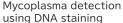


Mycoplasma detection using culture method



Viral CPE assay (in vitro)





Global Clinical Trials

We serve as a single point of contact for global clinical trials, providing projects with the same full-support system as our central laboratory services in Japan.

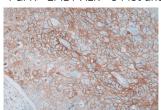
By linking up services with leading test centers throughout Asia, we can, for instance, offer accompaniment during Site Initiation Visits (SIVs), sample collections from sites, and more efficient international shipping costs, so that overseas clinical trials go forward smoothly.



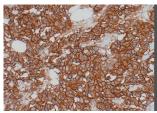
Biomarkers

We handle a wide range of biomarkers, including the following.

- · EGFR (HER1) · HER2/erbB2 · K-RAS · C-KIT (DNA)
- · FGFR · EML4-ALK · c-Met and more



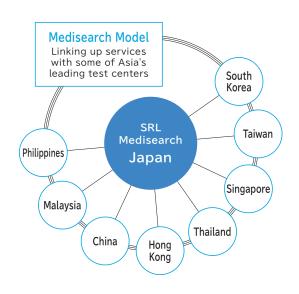
Breast cancer tissue EGFR (HER1)



Breast cancer tissue HER2/erbB2

Quality Tests

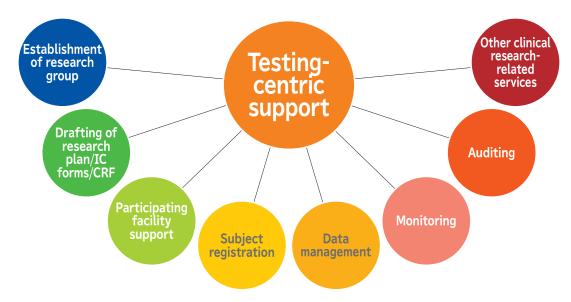
- 1) Sterility testing (Japanese Pharmacopoeia)
- 2) Mycoplasma testing (Japanese Pharmacopoeia, biological product standards)
 - · Culture methods, DNA staining, PCR
- 3) Endotoxin testing (Japanese Pharmacopoeia)
- 4) In vitro assays for CPE, HA and HAd
- 5) Virus-free testing
 - · HBV, HCV, HIV-1, HTLV-1 and B19V
- 6) Other tests (potency assays, etc.)
- We carry out tests at two different levels, according to the sponsor's requirements.
- 1. Study-related documents review by QAU in line with the reliability standards for application documents as stipulated under Article 43 of Pharmaceutical and Medical Device Act.
- 2. Tests at GLP facilities, carried out by GLP organizations (QAU for facility tests only)



Clinical Research Support

One-Stop Support for Clinical Research

We provide consistent support from the preparation stage all the way to the finish, focusing on the testing needed to build evidence for clinical research.



Establishment of Research Group

As a research office, we support all operations involved in the launching of the research, including preparations, scheduling, and kickoff meetings, through briefings with research representatives.

Drafting of Research Plan/IC Forms/CRF

We prepare drafts of any research plans, informed-consent-related briefing materials, and case report forms (CRF) needed for clinical studies.

Participating Facility Support

For participating facilities, we coordinate support for applications to ethical review boards and contracted research agreements. We also hold startup meetings and coordinate testing materials and operations, as well as briefings on the research protocol and methodology, and any other necessary coordination.

Subject Registration /Data Management

We create electronic data capture (EDC) systems for registering subject data and collecting survey items. We also manage data by controlling and coordinating operations throughout the duration of the research.

Monitoring

To control the quality of the research, we prepare monitoring plans in line with the research design, and conduct both central monitoring and onsite monitoring.

Auditing

We perform auditing according to audit plans in order to assure the quality of the research.

Other

Clinical research-related services

- · We have access to testing knowledge, testing techniques (SRL), and a nationwide sample collection network.
- We possess GCP-based project management knowledge, expertise, and skills, grounded in our experience with pharmaceutical development support and multicenter study support.
- · We command a wide-ranging network, including our Group and business partners.