Sodality Summary

Sodality Profiles

Name of Sodality: CSIA (Clinical Service In ASIA)

Establishment: 2015

Member Company:

[CSIA-SMO]
- Medical System Research Corp.（Japan）
- SitePartner Corporation（Taiwan）
- SMO ClinPlus Co., Ltd.（China）
- MedPlus1 Co., Ltd.（Vietnam）

[CSIA-CRO]
- SRD Co., Ltd.（Japan）
- GCP ClinPlus Co., Ltd.（China）
- MedPlus1 Co., Ltd.（Vietnam）

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Service Description: Contracted clinical research development services for pharmaceuticals, medical devices, quasi-drugs, in-vitro diagnostics, healthy foods, and cosmetics in health care industry

Greetings

Founder

Hiromi Tazawa

President & CEO,　SRD Co., Ltd.

CSIA supports with abounding experiences and utilizing original method centering the customer request and mutual trust.

Healthcare Market in Asia is rapidly expanding more than we expected by supporting of economical rapid growth in Asia. For tracking this rapid growth, CSIA is established to provide the One Stop Solution of Clinical Development Service to our customers by gathering the knowledge and knowhow of deeply rooted SMOs and CROs in each Asia region.

For corresponding with the change of clinical development trend, CSIA provides the services with adequate accuracy and quality using with flexibility and broad-ranging information networks to fulfill our customer needs in any therapeutic areas. It is our great pleasure that you would expect our outstanding future activities

Co-founders

Charlie Chen

Chief Executive Officer, GCP ClinPlus Co., Ltd.

CSIA provides truly integrated one-stop solution for our clients across Asia Pacific region, from site resources, protocol design, to Regulatory support.

Fiona Yu

Chief Executive Officer, SitePartner Corporation

By performing clinical trial in Asia, CSIA not only is more cost effective, but creates a high level of efficiency as well.

David Yang

Chief Executive Officer, SMO ClinPlus Co., Ltd.

The best solution for conducting a clinical study is "to do it in right way" rather than “to monitor”. SMO is an effective solution for most clinical studies in Asia. With our assistant, you will be able to accelerate the timeline and ensure the quality of studies .

Takeshi Abe

Chief Executive Officer, Medical System Research Corp.

As a pathfinder of SMO in Japan, we gradually expanding our capability in various therapeutic areas for providing adequate support to our customers Complying with ICH-GCP and ALCOA, etc. and are making effort to become close partner with our customers. With our conscientious support, you will receive higher quality service level with that of a competent SMOs.

Shinichi Tamura

President, MedPlus1 Co., Ltd.

Providing and performing high quality SMO/CRO services in accordance with ICH-GCP and local regulations in Vietnam. Especially in SMO services, CSIA will provide high quality services even you would request with high level requirements for your successful achievement.

Contract Research Organization

CSIA-CRO Member History

	SRD	GCP ClinPlus	SRD Group MedPlus1 Co., Ltd.
1989	• SRD Co., Ltd. was established with the capital of around 0.16 mil. USD		
1992	• Capital increased to 0.24 mil. USD		
1997	• Capital increased to 0.32 mil. USD		
1999	• Separated SMO service department as MSR		
2003	• SRD Biology Center (Non-clinical Lab Service) was established	• Beijing DMS Pharma Ltd was established	
2004	• IR Juhan (Real Estate) was established	• YiXie ZhongTai MedTech Consulting Ltd (Medical Device) was established	
2005	• SRD Biology Center, Shibukawa Laboratory was opened in Gummna		
2008	• 20th Anniversary	• Over 300 clinical trials successfully completed	
2009	• Capital increased to 0.4 mil. USD	• SMO business officially started	
2010	• International clinical trial support service started	• GCP ClinPlus was established by merging three companies	
2012	• SRD Staff (dispatch business) was established • Acquired 1st class medical device marketing authorization holder	• GCP USA was established	
2013	• International clinical trial support service is officially established as Dept. of Global Project Management • 25th Anniversary	• SMO ClinPlus separated as independent subsidiary of GCP ClinPlus with the capital of 0.16 mil. USD	
2014		• GCP US Operation Team started	• SRD established as a first authorized SMO in Vietnam with Shinichi Tamura (CEO) and the capital of 0.24 mil. USD • Hired >10 employees
2015	• Hired >200 employees • SRD elaborated CSIA plan for Asia clinical development	• GCP EU was established • Hired >200 employees • Covers 50 cities in China until 2015	
2016	• CSIA (Clinical Service In Asia) is established and all 3 companies above joined as member to support clients for accurate, smooth, and reliable clinical trial conductions • System developed for supporting small to large population of clinical trial in Asia • Covers main cities in Asia for potential clinical trial conductions		

Contract Research Organization

Service Center

THINK GLOBALLY ACT LOCALLY

- Customer-oriented Service Engagement

  CSIA-CRO will provide clinical development solutions for matching customer needs based on the customer request by constructing professional team from the US, Japan, China, Taiwan, Korea, and/or Vietnam. Professional team member will perform high quality service with effective operation for development support duties to achieve customer goals

- Service Portfolio

  Usually, Asian study or study including Asian countries were mainly supported or consulted by big global CROs. However, CSIA-CRO provides the service with high level know-how and high speed performance based on the experienced and cultivated information rooted by each local CROs

- Asia Network Service Model

  CSIA-CRO will provide best clinical development strategies as a solution to satisfy customer needs by collaborating with CSIA-SMO which has a network of strong partnership with local institutions. This model will be the first initiated service in the world, and will provide a high quality performance corresponding to the cultural background and legal requirements by local rooted CROs and SMOs

* CSIA will collect the information from several CROs in Korea and Taiwan for selecting service provider by the customer to satisfy the needs, and will operate clinical trial conducted in these countries.

Market Value

CSIA-CRO
is the pioneer of first Asia CRO group by integrating the clinical development with the Site Management Organization Group in ASIA

- Full Support Solution

  CSIA will perform a full clinical development support service with CSIA information exchange system which the customers have never experienced by using the effective mobility and flexibility of CRO and SMO which they closely and directly feel the rapid changing condition and environment of clinical development in Asia

- Quality Management

  CSIA will share all the issues such as protocol violations and adverse events occurred within participated countries and regions on the project level to increase the entire study quality. And the policy of the CSIA is to provide maximum benefit to our customer corresponding by risk-based and remote monitoring, and complying with ALCOA, ICH-GCP, and local laws and regulations

- Information Sharing System

  Using the certain system also used as training system , CSIA will provide any customer's product related information to the customer to achieve that the customer has never experienced such a high quality fast clinical development service

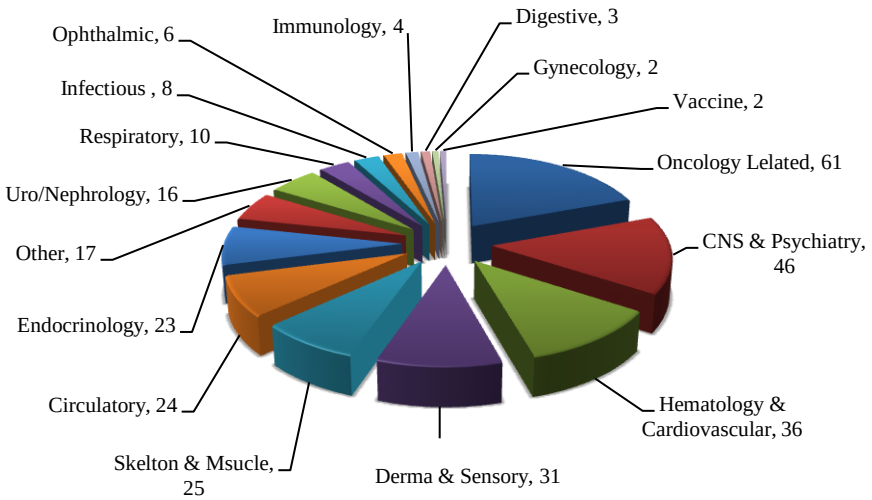
Experienced Therapeutic Areas

- Wide Variety of Disease Experiences and Asia Specialized Strategy

In General, mid sized CROs have a major issue to cover wide range of disease experiences by crossing the boarder, and to maintain and train the specialty as a CRO. CSIA-CRO, however, share the cultivated specialty within the 3 companies including IND submission to US-FDA to fulfill the customer satisfaction, also with additional information regarding the actual Asian clinical condition and environment from CSIA-SMO.
Over 1000 studies including the experiences from CSIA-SMO leads to set up the training system which is specialized in the subjective disease of our customer for providing the best performance with reliability. As a rooted CRO in each regions, CSIA-CRO will provide precious information to the customer by strong and good relationship with investigational institutions with cooperation of CSIA-SMO

*CSIA-CRO has been experiencing major disease such as oncology and CNS that are trends in clinical development all over the world, and cultivated all the related skills to satisfy customer needs.
It is very important for the customer that CSIA-CRO has a variety experiences to support various issues from the beginning to the end for achievement of the customer satisfaction.

Number of Studies in Each Disease Category



- Training System

CSIA-CRO will construct web-based training system specialized in the customer's developing product before its clinical study start (after finalization of the study protocol). The well-experienced and specialists in the CSIA-CRO will share the expected issues through the system and all the CRAs and CRCs who will involve the study will be able to access these system to be trained before the subject recruitment. After the study starts, the system is also able to use as a communication platform so that the customer also will access to supervise the study and to solve any issues timely for smooth and effective operation.

- Social Intercourse

CISA-CRO has a ordinarily 20 or more managers and leader who are experienced with various disease area, and most appropriate manager and leader will comprehensively control the study.
They are constructing close relationship for smooth and effective operation for the customer by having several social intercourse within three companies each year to provide the customer for easy control of entire cross boarder project

Contract Research Organization

Service Description

- Service of CSIA-CRO

CSIA-CRO provides a full support CRO service with reasonable price and tender care as equal service compared to the big global CRO to launch the customer's developing product even a little early from the beginning through the end including regulatory related tasks, medical writing, monitoring, and preparation of Common Technical Document.

Pharmaceutical Drugs

- Regulatory authority (RA) consulting
- Feasibility research
- Site selection
- Monitoring
- Quality control
- Subject registration and randomization
- Drug management
- Data Management
- Bio-statistics
- Medical writing
- Safety Management
- GCP audit
- Correspondence of document-based audit
- NDA Consulting
- NDA preparation support
- In-country clinical care taker

【Objectives】

- Phase I – IV clinical trials
- Clinical studies / researches
- Investigator initiated studies
- PMS

Medical Devices

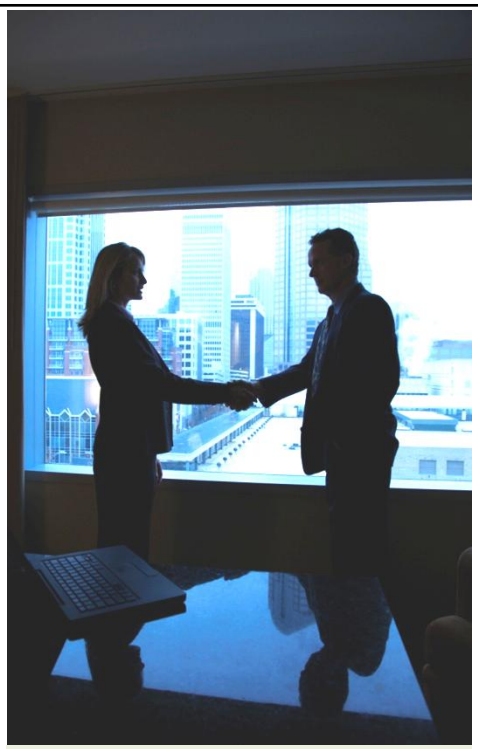
- China registration consulting
- Development consulting
- RA consulting
- Conformation of necessary test
- Feasibility research
- Site selection
- Monitoring
- Quality control
- Subject registration and randomization
- Device management
- Data Management
- Bio-statistics
- Medical writing
- Safety Management
- GCP audit
- Correspondence of document-based audit
- Consultation of application for approval
- Application documents preparation support
- In-country clinical care taker

Generic Drugs

- Development consulting
- Site selection
- Monitoring
- Quality control
- Subject registration and randomization
- Drug management
- Data Management
- Bio-statistics
- Medical writing
- GCP audit
- Correspondence of on-site audit
- Consultation of application for approval
- Application documents preparation support
- In-country clinical care taker

Others (Quasi-drugs, Cosmetics, IVD, Health Food)

- Site selection
- Monitoring
- Quality control
- Subject registration and randomization
- Drug management
- Data Management
- Bio-statistics
- Medical writing
- GCP audit
- Correspondence of on-site audit
- Consultation of application for approval



Bio-statistics and data management team is capable with SAS, IWRS, CDISC compliant EDC (E-clinicalOS, Inform, Viedoc), and MedDRA, and provide the service along with the customer needs. Also CSIA provides CTMS service upon the customer request to satisfy the needs of entire project management

*Please contact us for more details

Contract Research Organization

Description of Service Proposal

- Proposal of Clinical Trial Plan and Quotation

  CSIA-CRO will propose a clinical trial plan including all the information of member countries and regions based on the customers requests, and also more precious information with the cooperation from CISA-SMO. If the customer needs a consultation or has a intention to offer the project prior to the contract, CSIA-CRO will provide additional information to the customer .

Proposal Example of CSIA-CRO

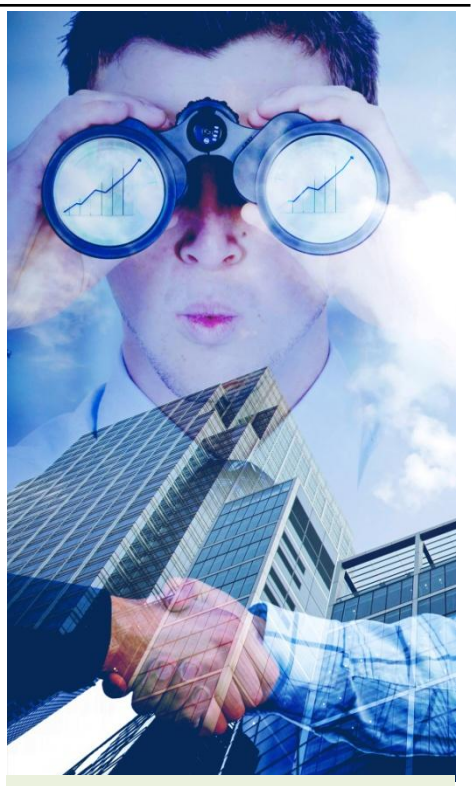
- Member company profiles
- Experienced disease area and achievements
- Trends and general regulation information
- General condition of requested disease in each countries
- Management plan
- Resource plan
- Recruitment plan
- Cost reduction scheme
- Risk management plan
- Consulting Service
  - RA consulting for requested project
  - Comprehensive milestone/ timeline set up until CTD submission

Mutual

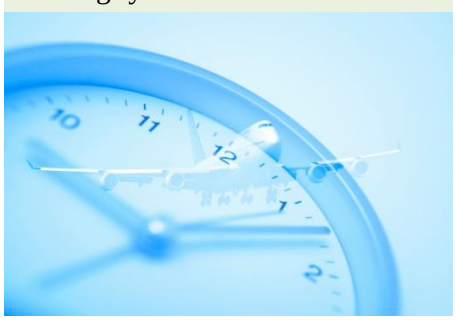
Cooperation

Example of Integrated Proposal of CSIA-CRO and CSIA-SMO

- Member company profiles
- Experienced disease area and achievements
- Trends and general regulation information
- General condition of requested disease in each countries
- KOL candidate list
- Candidate principle investigator and investigational sites
- Experiences of investigators
- Patients population of each sites
- Management plan
- Resource plan
- Recruitment plan
- Cost reduction scheme
- Risk management plan
- Consulting Service
  - RA consulting for requested project
  - Comprehensive milestone/ timeline set up until CTD submission



It will require large amount of service fee and resource to determine the potential of customer products in this rapidly changing development environment. CSIA will support the customer with reasonable price for providing strategy set up along with the situation of each countries and regions. CSIA will support you with every effort considering the future of customer developing product using CSIA information sharing system



*Actual proposals might vary based on the request.
*Feasibility research and China medical device registration orders will be consulted separately.

Contract Research Organization

Service Initiation Flow & Description

Step 1. Briefing Session with Customer

- Conclusion of non-disclosure agreement
- Sharing the demand / requirements and information from the customer within CSIA
- Consideration of the project conduction system / plan in CSIA
- Determination of the feasibility within CSIA
- Consideration and preparation of documents such for feasibility research, proposal, and quotation.

Step 2. Proposal of Clinical Trial System and Plan

- Obtaining further requests and demand from the customer as needed
- Integration of system, feasibility research questionnaire, quotations, and proposal
- Visiting the customer for proposal explanation as needed

Step 3. Conclusion of Trial Contract with Customer

- CSIA will set up the project team
- Establishment of web-based training system
- Implementation of project related training
- Preparation start for feasibility research or site selection

Step 4. Clinical Trial Request to Investigators

- Preparation start for candidate patient screening at the qualified sites
- Preparation start for IRB / EC submission
- Submission of application for IRB / EC
- Holing the clinical trial initiation meeting with customer

Step 5. Conclusion of Trial Contract with Investigators

- Conclusion of clinical trial contract with investigators
- Supplying necessary trial related materials and investigational products
- Starting patient recruitment