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.

Site Management Organizatior

CSIA-SMO Member History

MSR

1989
- SMO service established within SRD Co., Ltd.

1997
- Branch office opened in Maebashi, Gumma

1999
- MSR established (Service department separated by SRD Co., Ltd.)

SitePartner

2000
- SMO service established within PPC Group

2001
- MSR is admitted to SMONA
- Branch office opened in Osaka
- Established clinical operation in contracted sites
- SitePartner Corporation (SPC) established with the capital of 0.16 mil. USD

2004
- Yoshikazu Hinohara is inaugurated as Chief Executive Officer
- Hired > 30 employees and completed 80 clinical trials

SMO ClinPlus Site Management Organization

2004
- David Yang (CEO) promoted and started SMO service

2005
- Completed 100 clinical trials

2007
- Achieved study contracts with over 70 companies
- Fiona Yu (CEO) promoted SMO service in 2006
- Completed 200 clinical trials

2008
- Academic and social meeting are held for 10th anniversary
- Completed over 300 clinical trials
- Hired over 100 employees
- Completed 300 clinical trials

2009
- Academic conference are held for 5th anniversary
- SMO business officially established

2010
- Contracted with over 200 clinical sites
- Completed over 500 clinical trials
- Hired over 300 employees
- GCP ClinPlus Co., Ltd. was founded by combining 3 companies including SMO

2013
- Branch office opened in Yokohama
- Academic and social meeting are held for 15th anniversary
- Achieved study contracts with over 100 companies
- SMO ClinPlus established as a independent subsidiary of GCP ClinPlus with the capital of 0.16 mil. USD

2014
- Contracted with over 200 clinical sites
- Academic conference are held for 10th anniversary
- Addition of Excellent-Trial Operation Program (e-TOP) service for training

SRD Group MedPlus1 Co., Ltd.

2015
- Yoshikazu Hinohara is inaugurated as Chairman
- Takashi Abe is inaugurated as CEO
- Hired 198 employees
- Established department of Medical Tourism
- Branch office opened in Taichung city
- Completed over 750 clinical trials
- Hired >350 employees
- Capital increased to 0.66 mil. USD
- Hired >300 employees
- Covers 50 cities in China until 2015
- SRD established as a first authorized SMO in Vietnam with Shinichi Tamura (CEO) and the capital of 0.24 mil. USD
- Hired >10 employees

2016
- CSIA (Clinical Service In Asia) is established and all 4 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

Site Management Organization

Service Center

THINK GLOBALLY ACT LOCALLY

- Customer-oriented Service Engagement

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

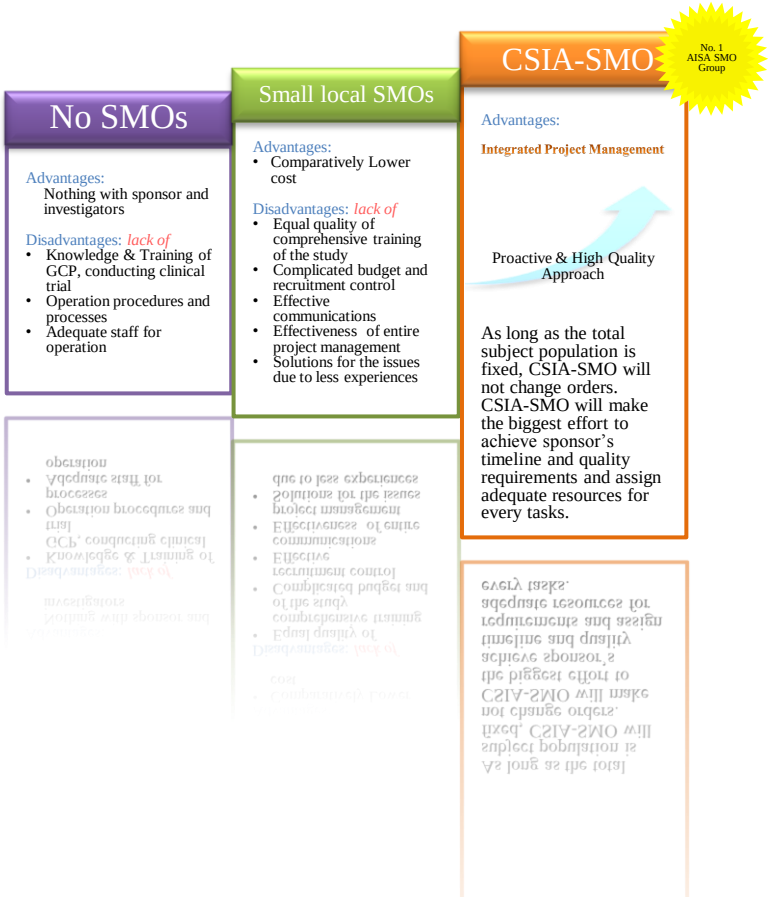
- Service Portfolio

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

- Asia Network Service Model

  CSIA-SMO will provide best clinical development strategies as a solution to satisfy customer needs by using strong relationship and collaborating 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 SMOs

Market Value



CSIA-SMO is the pioneer of 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 CRCs who closely and directly feel the rapid changing condition and environment of clinical development in Asia

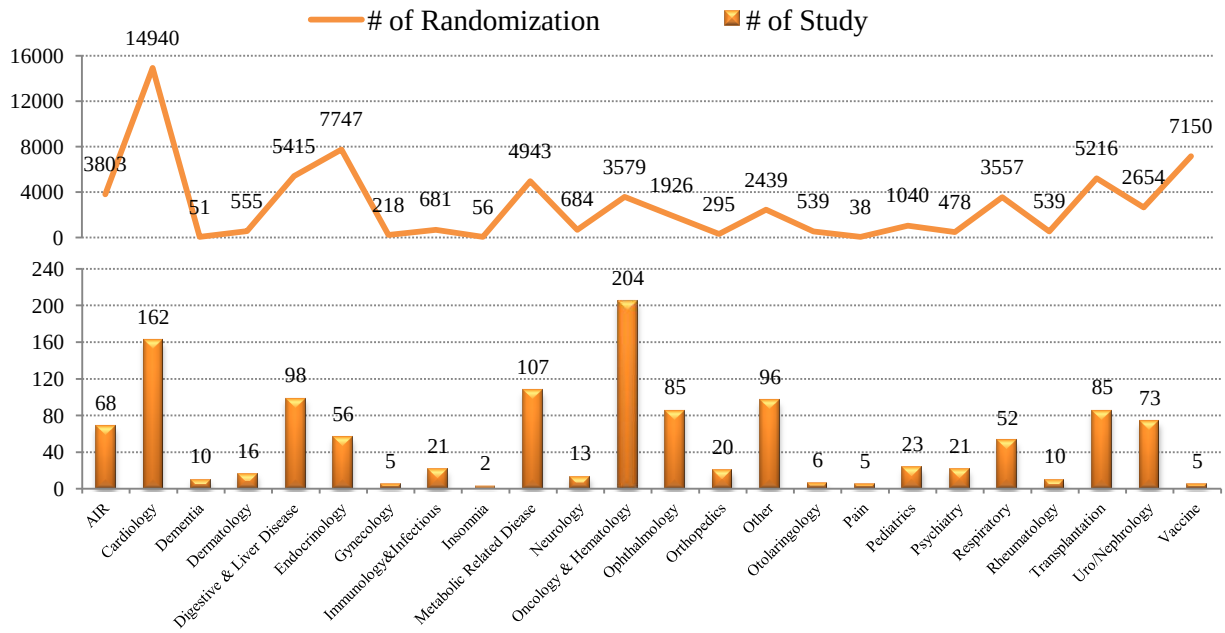
- Quality Management

  CSIA will share the 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, 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 The Strong Collaboration with Institutions in Asia Regions

  In General, SMOs have a major issue to cover wide range of disease experiences by crossing the boarder, and to maintain and train the specialty as SMO. CSIA-SMO, however, share the cultivated specialty within the 4 companies including the support experiences small venture to world big pharm. studies to fulfill the customer satisfaction, also with additional information regarding the actual Asian clinical condition and environment.
  Over 1000 studies leads to set up the training system which is specialized in the objective disease of our customer for providing the best performance with reliability. As a rooted SMO in each regions, CSIA-SMO will provide precious information to the customer by strong and good relationship with investigational institutions

- Social Intercourse

  CISA-SMO 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 four companies each year to provide the customer for easy control of entire cross boarder project

- Training System

  CSIA-SMO 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 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.

Site Management Organization

Service Description

- Service of CSIA-SMO

CSIA-SMO will manage the entire project and rapid patient recruitment from the beginning through the end of study by screening candidate patients with the selection of appropriate investigators and investigational sites from Japan, China, Taiwan, and Vietnam based on the request of our customer needs for this significantly changing health care industry in the world

CRC Service

It is the supporting service for investigators at investigational site for smooth study operation.
It is supporting tasks; nevertheless, CRCs are indispensable because they arrange / organize entire site operation for the site and sponsor for all the participants such as patients, investigators, site staff, and customer personnel.

- Preparing, archiving, and managing all the documentation such as ICF
- Supporting tasks of Investigators and site staff
- Organizing / arranging study related schedules
- Supporting the contact with sponsor
- Supporting the correspondence with audit from sponsors and regulatory authorities

, etc.

Clinical Trial Office Service

It is the supporting service for investigational site to operate the study smoothly; especially supporting for organizing clinical trail system, and preparing and managing documentation created during the study.

- Organizing clinical trial system
- Organizing clinical trial contract
- Preparing, archiving, and managing all the documentation
- Supporting the contact with sponsor
- Supporting the correspondence with audit from sponsor and regulatory authorities

IRB Office Service

It is the supporting service for institutional review board established by investigational site for smooth study operation; especially, preparing the documentation and operating IRB.

- Scheduling the date of IRB
- Preparation of materials for IRB and its management
- Proceedings of IRB
- Preparing and archiving IRB related documents
- Preparing the IRB meeting minutes

Pharmacology Service

All the representatives is working to keep making customers, investigational sites, and subjects for maximum satisfaction in mind to keep the high quality. It will lead more effective operation if CRO and drug level measurement company will be involved for customer developing products

- Study with healthy volunteers
- Study with the patients
- Study of patch test , etc.

Site Management Organization

Description of Service Proposal

- Proposal of Clinical Trial Plan and Quotation

CSIA-SMO provides a full support SMO service proposal including the information such as the necessary information usually from CROs at the study planning or before the study starts, and clinical environment which is obtained by CRCs who is really close to investigators and investigational sites in each regions with reasonable price and tender care as equal or better service compared to the big global CRO to launch the customer's developing product even a little early from the beginning through the end of study.

Proposal Example of 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

Mutual Cooperation

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

- 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

INTEGRATED PROPOSAL 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

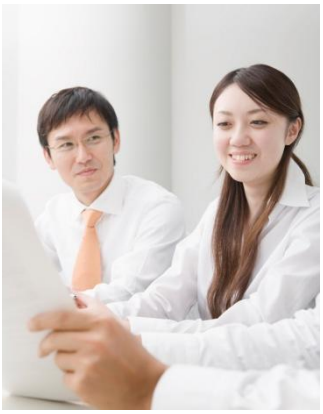
*Actual proposals might vary based on the request.
*Feasibility research and China medical device registration orders will be consulted separately.

Site Management 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
- Participating the clinical trial initiation meeting with customer

Step 5. Conclusion of Trial Contract with Investigators

- Handling and conclusion of clinical trial contract with investigators
- Receiving necessary trial related materials and investigational products
- Starting patient recruitment