The Regulatory Science Research Project on Pharmaceuticals and Medical Devices, funded by the Ministry of Health, Labour and Welfare of Japan
Research on improving the environment for the promotion of multinational clinical trials in the Asian region

"Survey on Environmental Preparation for Promoting International Collaborative Clinical Trials in the Asian Region"

Questionnaire (English)

This survey targets clinical trial sites (medical institutions) in the Southeast Asian region, which are considered to play a central role in clinical trials. It aims to elucidate the characteristics and challenges of clinical trial environments in various countries and key considerations for planning and conducting international collaborative trials. We kindly ask for your cooperation regarding the clinical trial system of your institution.

Please note, this survey is conducted as part of the Pharmaceuticals and Medical Devices Regulatory Science Policy Research Project funded by the Ministry of Health, Labour and Welfare of Japan. The findings will be compiled and are intended for publication in academic journals. Confidentiality of the survey will be strictly maintained, and no personal records will be disclosed.

Survey Content

1. Basic Information of the Medical Institution
- You may also provide facility brochures or similar documents containing the following information:

1-1. Type of Medical Institution
☐ Public (Government) Hospital ☐ University Hospital ☐ Private Hospital

1-2. Function Type of Hospital
☐ Hospital providing advanced medical care, developing and evaluating advanced medical technologies, and conducting training related to advanced medical care
☐ Small to medium-sized hospital supporting local healthcare in relatively small areas such as daily living zones
☐ Key hospital supporting regional healthcare, focusing on acute care in relatively large areas such as secondary medical zones
☐ Hospital specializing in rehabilitation medicine
☐ Hospital specializing in chronic care

☐ Hospital specializing in psychiatric care

☐ Hospital with palliative care wards or hospice facilities

1-3. Number of Beds

☐ Less than 50 beds ☐ 50 to less than 100 beds

☐ 100 to less than 200 beds ☐ 200 to less than 400 beds

☐ 400 to less than 600 beds ☐ 600 beds or more

1-4. Number of Patients

- Inpatients: [ ] Number of patients per day per hospital
- Outpatients: [ ] Number of patients per day per hospital

1-5.Number of Medical Staff

- Physicians: [ ] Number
- Nurses: [ ] Number
- Pharmacists: [ ] Number
- Other Medical Specialists: [ ] Number

1-6.Management of Medical Records

☐ Electronic Medical Records ☐ Paper Medical Records

2. Your Facility's Clinical Trial Experience

2-1. Experience in Domestic Clinical Trials (in the Past 5 Years)

☐ None

☐ Yes

If yes, please specify the number of trials for each phase:

- Phase I (or I/II): [ ] Number of trials
- Phase II: [ ] Number of trials
- Phase III (or II/III): [ ] Number of trials
- Phase IV (Post-Marketing): [ ] Number of trials

2-2. Experience in International Collaborative Clinical Trials (in the Past 5 Years)

☐ None

☐ Yes

If yes, please specify the number of trials for each phase:

- Phase I (or I/II): [ ] Number of trials
- Phase II: [ ] Number of trials
- Phase III (or II/III): [ ] Number of trials
- Phase IV (Post-Marketing): [ ] Number of trials

If you have experience in either 2-1 or 2-2, please provide further details:

2-3. Disease Areas of Clinical Trials Experience (in the Past 5 Years)

① Trials targeting infectious diseases: ☐ None ☐ Yes ⇒ [　] Number of trials,

② Trials targeting non-infectious diseases: ☐ None ☐ Yes ⇒ [　] Number of trials,

③ Trials targeting malignant neoplasms: ☐ None ☐ Yes ⇒ [　] Number of trials,

2-4. Experience with Regulatory Authority GCP Compliance Inspections (in the Past 5 Years)

☐ None

☐ Yes

If yes, please describe the nature of any issues identified, if applicable:

[　]

2-5.Experience with Sponsor Audits (in the Past 5 Years)

☐ None

☐ Yes

If yes, please describe the nature of any issues identified, if applicable:

[　]

3. Main Methods of Recruiting Participants for Clinical Trials at Your Facility (Multiple answers possible)

☐ Selection by primary physician

☐ Disease database

☐ Chart screening

☐ Recruitment advertisements

☐ Other (Please specify: [　])

4. Clinical Trial Execution System at Your Facility

4-1. Are there any public institutions supporting clinical trials other than regulatory authorities?

☐ No

☐ Yes

If yes, please describe the type of institution:

[　]

4-2. Does your facility have a specialized department supporting clinical trials?

☐ No

☐ Yes ⇒ Proceed to 4-3

4-3. Number of Staff in the Department Supporting Clinical Trials

Please indicate the number of staff in the department supporting clinical trials, including the number of staff who are capable of handling tasks in English.

	Full-time	Part-time	Staff capable of English communication
Physicians in the Clinical Trial Support Department			
Clinical Pharmacology Experts			
Clinical Research Coordinators			
Nurses in the Clinical Trial Support Department			
Pharmacists handling Clinical Trial Medication Management			
Administrative Staff			
Others			

4-4. Preparation of Procedure Manuals for Conducting Clinical Trials

① Is there a Standard Operating Procedure (SOP) established within your organization for conducting clinical trials?

☐ No ☐ Yes

② Is training provided for staff involved in clinical trials (e.g., GCP training)?

☐ No ☐ Yes

③ Are there established procedures for emergency response?

☐ No ☐ Yes

4-5. Facilities and Equipment Available for Clinical Trials

4-5-1. Facilities and Equipment for Clinical Trial Medication and Specimen Management

Please indicate the availability of the following facilities and equipment. If available, also inform us about the implementation of temperature control and the existence of systems to detect temperature deviations.

Availability of facilities/equipment		Yes/No	Is temperature control implemented and recorded?	Is there a system to detect temperature deviations?	Note
Clinical Trial Drug Storage	Refrigerator	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	Incubator	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	Freezer	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
Sample Storage	Refrigerator	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	Freezer	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
Cooling Centrifuges		☐ Yes ☐ No			
Humidity detector	Hygrometer	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	

4-5-2. Quality System

① Is internal quality control conducted and recorded within your facility?

☐ No ☐ Yes

② Do you undergo regular external quality control assessments?

☐ No

☐ Yes

If yes, please specify the external quality control programs you participate in:

☐ ISO 15189

☐ College of American Pathologists (CAP)

☐ Other (Please specify: [ ])

③ Has your facility obtained accreditation to the international standard ISO 15189?

☐ No ☐ Yes

4-5-3. Laboratory Equipment Available for Clinical Trials

Please indicate the availability of the following -medical equipments. If available, also inform us about the implementation of temperature control and the existence of systems to detect temperature deviations.

Available Equipment	Yes/No	Regular Inspection (Accuracy Management, Calibration, and Maintenance) Conducted and Recordable?	Note
Blood Pressure Monitor	☐ Yes ☐ No	☐ Yes ☐ No	
12-Lead Electrocardiogram (ECG) Machine	☐ Yes ☐ No	☐ Yes ☐ No	
X-Ray (Radiography) Systems	☐ Yes ☐ No	☐ Yes ☐ No	
Ultrasound Imaging Machine	☐ Yes ☐ No	☐ Yes ☐ No	
CT (Computed Tomography) Scanner	☐ Yes ☐ No	☐ Yes ☐ No	
MRI (Magnetic Resonance Imaging) Scanner	☐ Yes ☐ No	☐ Yes ☐ No	
PET (Positron Emission Tomography) Scanner	☐ Yes ☐ No	☐ Yes ☐ No	
Others			

4-6. Management of Essential Documents for Clinical Trials (such as source documents,

contracts, etc.)

① Is there a dedicated storage space for essential clinical trial documents?
☐ No ☐ Yes

② Is there a procedure manual for the storage of essential clinical trial documents?
☐ No ☐ Yes

③ Is there integration with the clinical system (electronic medical records)?
☐ No ☐ Yes

4-7. Is there an Internet environment available for clinical trials?

☐ No ⇒ Is installation possible? ☐ No ☐ Yes

☐ Yes

4-8. Are there any challenges or concerns regarding the collection and management of blood specimens for pharmacokinetics and biomarkers as specified in the clinical trial?

☐ None

☐ Yes

If yes, please specify:

5. Are there any available (participating) clinical trial networks?

☐ No

☐ Yes

If yes, please specify the type of clinical trial network:

6. If your facility has any appealing points as a clinical trial site, please describe them.
(Please describe the characteristics, strengths, and initiatives of your facility.)

7. If there are any challenges your facility faces as a clinical trial site, please describe them.

8. Information on Ethics Review Committee

8-1. Please specify the type and name of the Ethics Review Committee that reviews clinical trials at your facility.

8-2. Please specify the languages required for ethics review application documents.

1. Study Protocol: English / Local Language (specify)

2. Informed Consent Documents: English / Local Language (specify)
3. Investigational Medicinal Product Dossier: English / Local Language (specify)
4. Labeling of Investigational Medicinal Product: English / Local Language (specify)
5. Other Procedure Manuals: English / Local Language (specify)

9. CRC Support Activities

For the following tasks, to what extent are CRCs in your facility involved?
(0 = Not involved at all, 1 = Assist, 2 = Partially involved, 3 = Mainly responsible, 4 = Fully responsible)

(1) Assisting in the preparation of documents such as informed consent forms [ ]
(2) Subject screening and recruitment [ ]
(3) Assisting with informed consent process [ ]
(4) Schedule management [ ]
(5) Assisting with investigational product management [ ]
(6) Creation and management of case report forms (CRFs) [ ]
(7) Identification and reporting of adverse events [ ]
(8) Handling examinations and specimen collection [ ]
(9) Collection and entry of examination data [ ]
(10) Interaction with monitors [ ]
(11) Preparation and response for audits and inspections [ ]
(12) Handling subject inquiries [ ]
(13) Clinical trial document management [ ]
(14) Other (please specify: _____) [ ]

Thank you very much for your cooperation in this extensive survey. The information provided will be handled with care and compiled in a confidential manner.