Research project title: Survey on the Promotion of Multi-Regional Clinical Trials in Asia

Survey Questionnaire Sheet

This survey sheet is based on "Japan Pharmaceutical Manufacturers Association, Pharmaceutical Evaluation Committee, Clinical Evaluation Subcommittee Task Force 4, '16 Key Points Considered by Trial Requesters for the Future Environment of Medical Institutions for Clinical Trials' (September 2018)"
https://www.jpma.or.jp/information/evaluation/results/allotment/16key-points.html

A. Education for Medical Institution Staff

1. Do you actively and regularly conduct GCP education for staff at your medical institution?
Purpose of the question: This is to inquire whether the medical institution is proactively conducting GCP education (improvement of trial quality and protection of subjects), not just sponsor-led education.

☐ No ☐ Yes → "Proceed to 1-A"

1-A Please describe the specific methods, etc.
☐ We mandate regular GCP education.
→ Who is the main implementer of GCP education?
☐ Research Lead ☐ Clinical Trial Support Division/Centre ☐ Other (_____)

☐ We have defined methods and requirements for GCP education for medical institution staff.
→ Who set these standards?
☐ Head of the Research Institution ☐ Clinical Trial Support Division/Centre
☐ Other (_____)

If you're doing anything beyond the above, please let us know.

2. Do medical institution staff participate in trial-specific training and create records?

Purpose of the question: This is to inquire whether the medical institution staff involved in the clinical trial are actively participating in training and creating records to fulfill trial implementation requirements.

☐ No ☐ Yes → "Proceed to 2-A"

2-A Please describe the specific methods, etc.

☐ When new staff are added or trial protocol is revised, the physician in charge or the person appointed by them creates training records and Delegation Lists in a timely manner.

→ Please explain how the created records are stored.

☐ Staff keep individual records ☐ Stored collectively at the Clinical Trial Support Division/Centre ☐ Other (_____)

If you're doing anything beyond the above, please let us know.

3. Do all medical institution staff involved in the trial understand the procedure for reporting serious adverse events (SAEs) to the institution or the trial requester?

Purpose of the question: This is to inquire whether you have clearly established the procedures for handling SAEs in patients, and are prepared to implement them from the viewpoint of patient protection.

☐ No ☐ Yes → "Proceed to 3-A"

3-A Please describe the specific methods, etc.

☐ We have established and shared the procedure for reporting SAEs to the institution or the trial requester so that any medical institution staff member can properly handle SAEs.

→ Who is the main implementer of this initiative?

☐ Research Lead ☐ Clinical Trial Support Division/Centre ☐ Other (_____)

If you're doing anything beyond the above, please let us know.

4. Do you have a mechanism for sharing and accumulating knowledge and experience that helps improve clinical trial operations as an organization?

Purpose of the question: This is to inquire whether you have a mechanism to accumulate knowledge and experience gained through clinical trial operations in a place accessible at any time for anyone who wants to reflect, and to share within the institution, leading to improvement in data quality and efficiency of operations.

☐ No ☐ Yes → "Proceed to 4-A"

4-A Please describe the specific methods, etc.

☐ We record and share knowledge and experience from external training.

→ Who is the main implementer of this initiative?

☐ Clinical Trial Support Division/Centre ☐ Staff Team ☐ Other (_____)

☐ We share successful and unsuccessful examples of each trial throughout the institution to improve trial operations.

→ Who is the main implementer of this initiative?

☐ Clinical Trial Support Division/Centre ☐ Staff Team ☐ Other (_____)

If you're doing anything beyond the above, please let us know.

B. Regarding the Role Distribution of Medical Institution Staff

5. Are the details of the common hospital process from consent acquisition to the end of the trial documented separately from the SOP and regularly reviewed?

Purpose of the question: This is to inquire whether there is a system to clearly visualize and share among the medical institution staff the trial process, such as who does what and when, as many medical institution staff members with various roles are involved in implementing a clinical trial.

☐ No ☐ Yes → "Proceed to 5-A"

5-A Please describe the specific methods, etc.

☐ We create a process management sheet (a document that clarifies the overall flow of operations and who is responsible for each part of the operation) and review it regularly.

→ Who is the main implementer of this initiative?

☐ Clinical Trial Support Division/Centre ☐ Other (_____)

☐ We have a process management sheet as a template for the medical institution, which we customize and use according to the clinical trial protocol.

→ Who is the main implementer of this initiative?

☐ Clinical Trial Support Division/Centre ☐ Other (_____)

☐ We hold a meeting before the start of the trial to check the overall flow of the trial among the related departments and determine the roles of the related departments.

→ Who is the main implementer of this initiative?

☐ Research Lead ☐ Clinical Trial Support Division/Centre ☐ Support Staff like CRC

☐ Other (_____)

If you're doing anything beyond the above, please let us know.

6. Are all medical institution staff involved in clinical trials practicing ALCOA*?

*ALCOA: Requirements to prove data integrity (completeness of data) / Initials of "Attributable," "Legible," "Contemporaneous," "Original," and "Accurate"

Reference: Data Integrity and Compliance With Drug CGMP Questions and Answers Guidance for Industry | FDA (PDF)

https://www.fda.gov/media/119267/download

Purpose of the question: The thorough implementation of ALCOA is essential to ensure the reproducibility of the clinical trial process and to ensure "data reliability." This question asks about the practice of ALCOA in your hospital.

☐ No ☐ Yes → "Proceed to 6-A"

6-A Please describe the specific methods, etc.

☐ We clearly define the process of creating source documents, and the source documents are recorded in a state where the same clinical trial process can be reproduced even if a third party looks at them.

→ Who is the main implementer of this initiative?

☐ Research Lead ☐ Clinical Trial Support Division/Centre ☐ Support Staff like CRC

☐ Other (_____)

If you're doing anything beyond the above, please let us know.

7. Do you have a system in place to create Case Report Forms (CRFs) smoothly and accurately, and are you able to implement it?

Purpose of the question: The responsible physician has a duty to ensure the timely creation of CRFs and the reliability of data. This question asks whether you have established a system to create and check CRFs in collaboration with medical institution staff.

☐ No ☐ Yes → "Proceed to 7-A"

7-A Please describe the specific methods, etc.

☐ Procedures are defined from the time of the subject's visit or occurrence of adverse events to the creation of source documents and CRFs to ensure timely and accurate creation of CRFs.

→ Who is the main implementer of this initiative?

☐ Research Lead ☐ Clinical Trial Support Division/Centre ☐ Support Staff like CRC

☐ Other (_____)

☐ The double-check system for CRF creation (e.g., rechecking after some time if there is only one person) is well known and thoroughly implemented.

→ Who is the main implementer of this initiative?

☐ Research Lead ☐ Clinical Trial Support Division/Centre ☐ Support Staff like CRC

☐ Other (_____)

☐ In addition to the main CRC, a deputy CRC is assigned, and the CRF is created independently within the period requested by the clinical trial requester.

→ Who is the main implementer of this initiative?

☐ Research Lead ☐ Clinical Trial Support Division/Centre ☐ Support Staff like CRC

☐ Other (_____)

☐ The responsible physician conducts a final check, particularly on content related to safety and key evaluation items, before signing to guarantee the content of the CRF.

If you're doing anything beyond the above, please let us know.

8. Do you have a system in place to administer the investigational drug properly to the subject?

Purpose of the question: This question asks whether you have a system in place to prevent mistakes such as misadministration by ensuring that medical institution staff involved in prescribing, dispensing, and providing/administering investigational drugs understand their roles correctly, after establishing a system for managing investigational drugs (securing storage locations, temperature and inventory management, handling when the investigational drug manager is not present, etc.).

☐ No ☐ Yes → "Proceed to 8-A"

8-A Please describe the specific methods, etc.

☐ The people involved in the transport and collection (doctors/pharmacists/CRCs, etc.) confirm their respective job allocations at the start of the trial and during its implementation.

If you're doing anything beyond the above, please let us know.

C. Staffing and Talent Acquisition

9. Do you have a system to cross-evaluate the characteristics of the trial (trial schedule, disease area, difficulty, etc.), risk, and the aptitude/workload of the medical institution staff and allocate resources appropriately for each individual trial?

This question is about whether you have a system in place to distribute tasks, including the use of external resources, by cross-evaluating the workload, considering the experience, qualifications, and skills of each staff member.

☐ No ☐ Yes → "Proceed to 9-A"

9-A Please describe the specific methods, etc.

☐ Discussions on personnel reallocation related to trial tasks are held in accordance with the progress of the trial.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center

☐ Other ( )

☐ After estimating the workload from the trial schedule, difficulty, subject enrollment schedule, and Visit plans, resource planning is formulated.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center

☐ Other ( )

☐ There is a system in place to ensure that the support system for a single project is not composed only of new CRCs.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center

☐ Other ( )

☐ For international collaborative trials, there is a system to allocate staff who are proficient in foreign languages.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center
☐ Other ( )

If you're doing anything beyond the above, please let us know.

D. About the structure of the medical institution

10. Do you independently perform accuracy management of the equipment and devices used in the trial and keep the records?

The intention of the question: This question asks whether a system is in place for regular accuracy management of devices to ensure data reliability, and whether those records are appropriately stored.

☐ No ☐ Yes → "Proceed to 10-A"

10-A Please describe the specific methods, etc.

☐ The person in charge of management maintains records of equipment and device accuracy management, and performs inspections and updates records as necessary.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ CRC team
☐ Other ( )

If there is anything else you are doing beyond the above, please let us know.

11. Does the medical institution staff have a system to consider CAPA (Corrective and Preventive Action) and share information after a deviation from the clinical trial protocol or an in-house procedure violation has occurred?

Intention of the question: When a deviation from the clinical trial protocol or a violation of an in-house procedure occurs, it is necessary to contact the event occurrence (in-house contact, contact to the trial requester), identify the cause, develop CAPA, and share CAPA information. This question asks whether a system has been established to work on CAPA throughout the hospital.

☐ No ☐ Yes → "Proceed to 11-A"

11-A Please describe the specific methods, etc.

☐ We have created a procedure manual for the in-house process at the time of deviation from the clinical trial protocol or when a violation of an in-house procedure occurs.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center

☐ Other ( )

☐ We have set up an organization or meeting to consider CAPA.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center

☐ Other ( )

☐ We have decided how to share CAPA (setting up meetings, etc.).

→ Please tell us how you do this.

Method:

If there is anything else you are doing beyond the above, please let us know.

12. Do you have a mechanism to prevent fraud as a medical institution?

☐ No ☐ Yes → "Proceed to 12-A"

12-A Please describe the specific methods, etc.

☐ We regularly share and discuss information on compliance, such as fraudulent cases, among medical institution staff.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ CRC team
☐ Other ( )

If there is anything else you are doing beyond the above, please let us know.

13. Is there a system to evaluate medical institution staff based on their contribution to clinical trials?

Intention of the question: This question asks whether there is a system to improve the motivation of medical institution staff towards clinical trials.

☐ No ☐ Yes → "Proceed to 13-A"

13-A Please describe the specific methods, etc.

☐ Before the start of the clinical trial, we evaluate the degree of involvement of each department (clinical trial department, other departments, nursing department, examination department, radiology department, clinical trial management room, etc.) and document the distribution ratio of research expenses under agreement.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center
☐ Other ( )

☐ We recognize doctors and others with high contributions in terms of the number of consents obtained and achievement rate.

→ Please tell us who is responsible for implementing this initiative.

☐ Head of Research Institution ☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ Other ( )

☐ Research funds are distributed to the medical department.

→ Please tell us who is responsible for implementing this initiative.

☐ Head of Research Institution ☐ Clinical Trial Support Department / Center
☐ Other ( )

☐ There is support for participation in training sessions.

→ Please tell us who is responsible for implementing this initiative.

☐ Head of Research Institution ☐ Principal Investigator ☐ Clinical Trial Support Department / Center
☐ Other ( )

If there is anything else you are doing beyond the above, please let us know.

14. Do you have a system to present a feasible number of cases based on clear evidence before undertaking a clinical trial?

Intention of the question: This question is about whether there is a system to understand the achievable contracted number of cases before deciding to undertake a clinical trial.

☐ No ☐ Yes → "Proceed to 14-A"

14-A Please describe the specific methods, etc.

☐ We respond after conducting chart screening and checking receipts.
→ Please tell us who is responsible for implementing this initiative.
☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ CRC
☐ Other ( )

☐ We respond after confirming with multiple doctors.
→ Please tell us who is responsible for implementing this initiative.
☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ CRC
☐ Other ( )

☐ In regular medical practice, we ask patients if they would be interested in a clinical trial if one were available, and list the responses.
→ Please tell us who is responsible for implementing this initiative.
☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ CRC
☐ Other ( )

☐ We have created a patient panel.
→ Please tell us who is responsible for implementing this initiative.
☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ Other ( )

If there is anything else you are doing beyond the above, please let us know.

15. Do you have a system that can screen all patients in the hospital without omission?

Intention of the question: This question is about whether there is a system for screening all potential patients in the hospital without omission.

☐ No ☐ Yes → "Proceed to 15-A"

15-A Please describe the specific methods, etc.

☐ We have opportunities to confirm the presence or absence of potential patients within the department.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ CRC

☐ Other ( )

☐ Screening is implemented even for cases in other departments.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ CRC

☐ Other ( )

☐ Regular chart screening is conducted by CRC, etc.

If there is anything else you are doing beyond the above, please let us know.

16. Do you create a case registration plan before the start of the clinical trial, and implement measures to promote case registration when case registration is struggling?

Intention of the question: This question is about whether there is a system to make a case registration plan from before the start of the clinical trial and take appropriate measures when there is a delay from the plan, in order to surely achieve the contracted number of cases.

☐ No ☐ Yes → "Proceed to 16-A"

16-A Please describe the specific methods, etc.

☐ We are implementing efforts to promote referrals from other hospitals (sending letters to other hospitals, utilizing local networks, etc.).

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ CRC

☐ Other ( )

☐ We are implementing efforts to find potential patients within the hospital (recruiting patients through posters, websites, etc.).

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ CRC

☐ Other ( )

☐ We regularly review chart screening methods (including changes in search conditions).

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ CRC

☐ Other ( )

☐ We are making a plan for subject registration considering the results of screening and the acceptance situation of competing clinical trials.

→ Please tell us who is responsible for implementing this initiative.

☐ Principal Investigator ☐ Clinical Trial Support Department / Center ☐ CRC

☐ Other ( )

If there is anything else you are doing beyond the above, please let us know.

E. About the Institutional Review Board (IRB)

17. Please tell us about the review by the IRB for international collaborative clinical trials.

① About the IRB to which the review is requested

※ Please check the applicable items.

☐ Reviewed by IRB installed in our institution

☐ Utilize central IRB → What percentage is it? (%)

☐ Other ( )

② About IRB review materials

Are the reviews conducted in English?

☐ No ☐ Yes → What percentage is it? (%)

(Free Description Field)
Please write down any opinions you may have on the establishment of an environment for promoting international collaborative clinical trials in the Asian region, as well as any problems or issues you are struggling with.

Thank you for your cooperation in the survey.

The information you provided will be treated as valuable data towards the establishment of an environment for promoting international collaborative clinical trials in the Asian region, and will be collated accordingly.

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