Recommendations for Strengthening Human Capital Development for Clinical Trials to Prepare for Future Health Crises

Advancing the strategy for implementing the Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization

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Executive Committee on Global Health and Human Security

Task Force for Promoting Pharmaceutical and Medical Device Regulatory Harmonization in Asia

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Abstract

The COVID-19 pandemic highlighted the importance of international cooperation and specialized human capital[1] for ensuring prompt and efficient responses to global health crises. To prepare for the next pandemic, it is essential that Japan promote international joint clinical trials, develop capable leadership, and secure and cultivate the necessary human capital. The need to ensure capacity to conduct rapid clinical trials in an infectious disease emergency is closely connected to the government of Japan's recent decision to establish the Japan Institute for Health Security (JIHS), which will merge the National Institute of Infectious Diseases and the National Center for Global Health and Medicine (MHLW, 2023), and will promote the development of a clinical trial network in Japan and conduct international joint clinical trials. Preparedness for the next pandemic will also require conducting regular clinical trials during non-emergency times and building capacity through the accumulation of practical know-how, dispatching personnel to foreign institutions, and so on.

In light of these requirements, the Task Force for Promoting Pharmaceutical and Medical Device Regulatory Harmonization in Asia offers the following recommendations:

1. Cultivate core human capital (e.g., lead researchers, staff of central support institutes, staff of medical institutions)
2. Run emergency simulations and use those opportunities to train human capital
3. Build capacity through the implementation of regular clinical trials
4. Build capacity by dispatching and exchanging personnel with foreign institutions
5. Ensure the mobility of diverse human capital within and between facilities
6. Strengthen the infrastructure (e.g., secure human capital by improving compensation, career paths, etc.)

[1] As the staff involved with clinical trials generate new value in the form of public good through their activities, this recommendation describes them as "human capital" (人財) instead of "human resources" (人材), except where the "human resource" is used as a proper noun.

Furthermore, it is important for all stakeholders to strengthen collaboration not only with the new JIHS but also with the medical institutions that make up the clinical trial network, clinical research core hospitals, and national centers. To strengthen Japan's preparedness to deal with health crises, there needs to be cooperation between the government, academia, the Pharmaceuticals and Medical Devices Agency (PMDA), pharmaceutical companies, contract research organizations (CRO), site management organizations (SMO), and other stakeholders. Human resource development initiatives directly contribute to future medical innovation and responses to global health issues. By cooperating with the international community to develop human capital with a diverse range of specializations, we can forge a path toward improving global health and achieving the Sustainable Development Goals.

Background

As the host of the G7 in 2023, Japan emphasized each country's shared responsibility and the need for international cooperation to achieve universal health coverage (UHC). To achieve that, they developed a UHC global plan and took other actions to promote UHC in the global community (MHLW, 2023a). While Japan has shown global leadership on global health, however, Japan's development of COVID-19 medical countermeasures (MCMs) was inadequate, and in the field of research and development (R&D), it has become increasingly clear that Japan's domestic and international cooperative systems face several challenges.

The Task Force for Promoting Pharmaceutical and Medical Device Regulatory Harmonization in Asia (hereafter, Task Force) was established in 2018 under the Executive Committee on Global Health and Human Security, a public-private collaboration platform on global health policies organized by the Japan Center for International Exchange (JCIE). Since that time, it has published recommendations that contributed to the development of the Japanese government's Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization. It has also presented recommendations on pharmaceutical regulatory harmonization and the development of a network of clinical trial facilities in the Asian region (Task Force, 2019), as well as offering an execution strategy aimed at realizing that objective (2020). It has provided recommendations on ways to enable the rapid development and supply of MCM when a pandemic occurs due to an unknown infectious disease (2021), as well as recommendations aimed at developing and expanding Asian hubs to support that type of urgent response (2023). Building on its previous work, and based on the experience to date with pandemics, the Task Force began in September 2023 to discuss issues that must be addressed to better respond to future emergencies and identified the following areas as requiring stronger initiatives:

- international cooperation during non-emergency times to rapidly share pathogens, sample data, epidemiological information, etc.
- comprehensive and seamless R&D support systems to create drug discovery ecosystems that take into account pharmaceutical regulation and approval processes

- development of regulations and infrastructure in manufacturing and production and modularization in the post-approval manufacturing processes
- strengthening of domestic and international clinical data networks, the digitization of clinical trials, and international cooperation in decentralized clinical trials
- strengthening of academic research organization (ARO) functions and human capital development for researchers and research support personnel
- human capital development and strengthening of cooperation for public health measures, emergency assistance, etc.

Since the Task Force began examining these issues, there has been progress made by the government of Japan on several valuable fronts, such as the formation of world-class R&D hubs for vaccine development (AMED/SCARDA, 2024), various efforts on digitization (MHLW 2023b), and deliberations at the PMDA toward the establishment of hubs in other countries (MHLW 2023c). Discussions have also been held by the government's expert panels regarding critical issues for accelerating R&D. In addition, the JIHS is to be established in 2025, and international joint clinical trials are to be further promoted in a range of fields, including infectious diseases.

In light of the developments above, the Task Force recently held discussions focused on an area that has not received much attention from the Japanese government to date: namely, what should be done to implement adequate measures, based on a comprehensive and consistent strategy, to develop the necessary research and research support personnel and to maintain and enhance ARO functions. Based on their discussions, the Task Force offers the following recommendations.

Recommendations

1. The types of human capital that must be developed

To handle clinical trials led by Japan or other countries, it is necessary to have a network that functions organically. This requires developing three types of human capital in a balanced manner: (1) researchers to lead the clinical trials ("research leaders"); (2) staff responsible for central support organizations ("central support staff"); and (3) staff responsible for clinical trials at participating institutions ("local support staff"). At the same time, with regard to clinical staff who treat patients in clinical settings, another important issue is improving awareness of clinical trials through training and other measures.

1.1 Research leaders to conduct the clinical trials necessary in emergencies

To facilitate the various clinical trials required during an infectious disease emergency, it is essential to have research leaders who not only are able to generate their own ideas for research and formulate plans but who also possess the necessary practical knowledge and know-how related to clinical trials (e.g., regulatory requirements, ethics, biostatistics, and quality management), the aptitude to negotiate with companies to acquire funding, and the ability to participate in steering committees for international clinical trials and to head up Japan-led clinical trials. During an emergency, the government requires clinical trials for the purpose of public health policymaking rather than academic research. Deploying and developing research leaders who can play that central role is a pressing issue.

To ensure that these types of research leaders can acquire the essential qualities and skills requires both systematic learning and on-the-job training (OJT). In addition to building up experience by taking the lead in clinical trials during non-emergency times (not necessarily limited to the field of infectious diseases), it is also essential to develop human capital through the type of overseas dispatch programs discussed under Recommendation 4 below, "Building capacity through dispatch and exchange of personnel with foreign institutions." In this respect, it is also critical during that training period to create a system to engage Japanese and foreign mentors with excellent knowledge and character and a proven track record in this field to provide those trainees and peers with advice and inspiration as necessary.

1.2 Staff responsible for central support organizations (central support staff)

In particular, the JIHS will need to play the role of a central support organization for the clinical trial network in the field of infectious diseases. To do so, it must function (1) as the headquarters of Japan's domestic clinical trial network; (2) as the headquarters for Japan-led clinical trials; and

(3) as the coordinating center responsible for facilitating Japan's participation in foreign-led clinical trials. Fulfilling this role requires ARO staff, including study managers, biostatisticians, monitors, data managers, and safety management specialists.

When conducting joint clinical trials on an international basis, study managers capable of coordinating with people in other countries play a particularly significant role. They require knowledge and skills that are different from those normally required for clinical trials in Japan, such as linguistic abilities as well as proficiency in handling contracts with foreign medical institutions and CROs, among others; familiarity with import and export procedures for drugs and medical specimens; and the ability to acquire permits and licenses relating to the conduct of clinical trials from local regulatory agencies. When securing and training study managers who can work on clinical trials, it is important that they gain practical experience in various roles in clinical trials, as well as strengthening their linguistic abilities, negotiation skills, and communication capabilities needed to engage with research institutions and vendors in other countries. These abilities will be of immediate use when conducting clinical trials with other countries, and so measures to nurture such skills must be implemented as a top priority. Furthermore, to enable study managers to participate in conducting clinical trials promptly in the event of an emergency, it is necessary to build a global human network during non-emergency times.

A career advancement ladder should be developed whereby staff who have acquired experience in trials in Japan take charge of clinical trials as the next stage in their career development. It is also necessary to consider strategies for leveraging foreign human capital when negotiating with foreign institutions, while also building mechanisms to secure and cultivate talent so that AROs function as a team.

Realistically, the JIHS cannot maintain all of the functions necessary in emergencies during non-emergency times. Therefore, we must discern which functions can be outsourced and which must be provided internally and focus on the development of the human capital necessary for the latter. At the same time, we should run simulations considering the outsourcing of work to external CROs and SMOs as well as AROs at other institutions in order to identify the capacity necessary for expanding personnel during emergencies (i.e., surge capacity).

1.3 Staff responsible for clinical trials at participating institutions (local support staff)

Each medical institution within the clinical trial network must secure the necessary human capital—such as clinical research coordinators (CRCs) who are involved in running clinical trials, and personnel for the secretariat of committees related to ethical review processes, such as the Institutional Review Boards—and must encourage education on the participation in and reviewing of international joint trials. While some medical institutions have already secured a certain amount local support staff through their involvement in clinical trials for diseases other than infectious diseases, some have also utilized staff dispatched from SMOs to handle the practical affairs of clinical trials. However, in the latter case, it should be noted that such medical institutions do not retain any know-how once that staff leaves. For that reason, it is necessary to consider measures (including the provision of funding) to ensure that facilities that will serve as hubs in

the clinical trial network can secure and develop CRCs. In this respect, the United Kingdom's RECOVERY trial (Nuffield, n.d.) provides a valuable reference for Japan. One of the factors in the success of this trial was that the National Institute for Health and Care Research (NIHR) provided funding for medical institutions to employ research nurses during non-emergency times and those nurses supported data collection during the pandemic (NIHR 2022; Peto et al., 2022).

2. Developing human capital through emergency simulations

2.1 Developing human capital via simulations in line with the 100 Days Mission

The 100 Days Mission[2] is an internationally recognized goal of having MCMs available for use within 100 days of the World Health Organization (WHO) declaring a "public health emergency of international concern" involving a new infectious disease. This involves getting approval on rapid diagnostic tests, therapeutics, and safe and effective vaccines, and establishing effective treatment methods. International cooperation is essential to executing the 100 Days Mission. In that context, the roles and tasks required of the JIHS and of the clinical trial network that Japan intends to develop must be clarified, as well as the competencies required of researchers and ARO staff. To do so, it is necessary to carry out training during non-emergency times to clarify the roles of each profession through the development of prototypes for research plans and procedure manuals and by carrying out simulations (MHLW, 2021; AMED, 2023).

2.2 Division of roles by type of clinical trials

Many types of research are needed in the event that a new infectious disease emerges. In fact, in the initial stages of the spread of COVID-19, attempts were made to reposition existing pharmaceuticals through large-scale clinical trials, after which vaccines and new antiviral drugs appeared. The roles that will be required of the JIHS and the clinical trial network seem to differ, with the former progressing under the leadership of academia, and the latter being relatively dominated by companies and CROs.

In the initial stages of the outbreak of an emerging infectious disease, it is necessary to move rapidly to launch diagnostic method assessments and epidemiological research on the disease, as well as to conduct drug repositioning trials for existing pharmaceuticals. For the latter, participating in platform trials like REMAP-CAP[3] during non-emergency times is important. It is also important to foster the capacity to launch Japan-led platform trials in case a future epidemic is centered in Japan, or an infectious disease emerges that is peculiar to Asia.

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[2] For information on the 100 Days Mission, visit the International Pandemic Preparedness Secretariat website, https://ippsecretariat.org/.

[3] REMAP-CAP stands for Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia. For further information, visit https://www.remapcap.org/.

In the next phase, vaccines and new therapeutics must be developed. In the Phase 1 clinical trial stage, the JIHS should develop assay systems that are useful for pharmaceutical development and that can be proposed to the WHO as standards, such as antibody titer measurements for vaccines at a stage before clinical trials. It would also be beneficial for MCM R&D if the JIHS had a system to facilitate smooth technology transfer to private-sector laboratories for such assay systems developed by the JIHS. There may also be cases where it is useful to assess infection prevention effects in small-scale challenge trials in order to effectively screen candidate vaccines (Killingley et al., 2022). Furthermore, in an infectious disease outbreak, we can envisage therapeutic drug development and clinical trials of vaccines to evaluate their onset prevention effects after Phase 2 trials in conditions where the number of those infected in Japan is not necessarily large. It is also worthwhile to prepare for emergencies by positing the emergence of an infectious "Disease X" in Asia and promoting research into the international registry of known infectious diseases specific to Asia. It is important to conduct simulations that are conscious of the types of clinical trials that may emerge and confirm the roles, tasks, and necessary capabilities for each in order to develop the human capital that will be required.

3. Building capacity through regular clinical trials

3.1 Accumulating know-how through regular clinical trials

During non-emergency times, the field of infectious diseases suffers a dilemma insofar as it has few products in development, making it difficult to conduct multiple clinical trials on a regular basis. In contrast, during emergency situations, it is necessary to conduct multiple clinical trials at the same time. On the other hand, given that the JIHS and the medical institutions comprising the clinical trial group also handle noncommunicable diseases during non-emergency times, they need to accumulate know-how by conducting clinical trials on a regular basis, including on diseases other than infectious diseases. During the COVID-19 outbreak, some countries temporarily suspended clinical trials for non-urgent diseases (Audisio et al., 2022). As such, it is necessary to conduct clinical trials on both infectious and non-infectious diseases during non-emergency times, and then shift resources related to clinical trials to concentrate on emerging infectious diseases during an emergency.

3.2 Combining systematic learning and OJT

Although the basics of conducting and supporting clinical trials can be acquired through systematic learning, such as lectures, practical knowledge and know-how can only be attained through involvement in clinical trials. With respect to the former method, there are various types of training materials and resources that can be used for physicians, senior CRCs, data managers, auditors, and chairpersons/members of ethics review committees. These resources are provided by the clinical research core hospitals certified under the Medical Care Act as the Comprehensive Projects for the Promotion of Clinical Research, as well as e-learning websites like the APRIN e-

Learning Program (eAPRIN), ICR Clinical Research Introduction (ICRweb), and the Clinical Research Online Professional Certification Program at Osaka University (CROCO).[4]

Conversely, some skills—including the planning of clinical trials, research support, quality control, and communication with stakeholders—can only be obtained through the practice of clinical trials. For this reason, OJT should be strengthened by regularly conducting clinical trials in the JIHS-led clinical trial network, and know-how should be gained through this process. In addition to the researchers and ARO staff who lead the research, the accumulation of know-how must include those in all relevant professions, including other researchers, CRCs, and clinical staff (e.g., the physicians, nurses, pharmacists, and others who perform clinical trials on patients) at the medical institutes that make up the clinical trial network.

4. Building capacity through dispatch and exchange of personnel with foreign institutions

In order to facilitate Japan's participation in clinical trials led by other countries in the event of an emergency, it is necessary to strengthen relationships with leading medical institutions abroad during non-emergency times. From FY2024, the Japan Agency for Medical Research and Development (AMED) plans to conduct an overseas dispatch program for personnel related to clinical trials (AMED, 2024). This program will provide research grants that will enable the long-term dispatch of physicians, study coordinators, and biostatisticians involved in clinical trials to major medical institutions in the United States and Europe. Such long-term human resource dispatch programs are extremely useful mechanisms for preparing for emergencies by strengthening relationships with the United States and Europe, and it is essential that they continue to be implemented consistently and reliably.

The distinctive character of the field of infectious diseases is that it requires clinical trials be conducted in areas where diseases are endemic. As such, it can be assumed that trials will need to be conducted in low- and middle-income countries (LMICs) in particular. As countries where diseases are endemic may not be English-speaking countries, it is essential to develop human capital with study management skills and experience in such an environment, including working with local staff and CROs. Therefore, if Japan can take the lead and gain experience in clinical trials in Asia and Africa during non-emergency times, it will greatly strengthen Japan's ability to conduct clinical trials during emergencies. With this in mind, it is essential that the aforementioned long-term overseas dispatch program proactively work to send human capital to foreign institutions that are conducting numerous international joint clinical trials in the field, such as Oxford University, the US National Institute of Allergy and Infectious Diseases, the Pasteur Institute, the European & Developing Countries Clinical Trials Partnership, and the European Vaccine Initiative. Medical research institutions in LMICs, including institutions where Japan has supported capacity building for many years through official development assistance (ODA), have expectations for conducting joint clinical research and trials with Japan. Therefore, efforts

[4] These sites are provided by the Association for the Promotion of Research Integrity (APRIN) (https://www.aprin.or.jp/en/e-learning_en), National Cancer Center (https://www.icrweb.jp/my/index.php), and Osaka University Hospital (https://bvits.dmi.med.osaka-u.ac.jp/croco/login.aspx) respectively.

should be made to build trust-based and cooperative relationships among human capital on both sides during non-emergency times through initiatives that offer benefits to the LMICs as well, such as technical cooperation and joint research. Accumulating experience in LMICs is also an effective means of developing Japan's human capital.

In addition to these long-term dispatch projects, human resource development programs for clinical trials are being conducted in the United States and Europe that span several days or several weeks. Japanese researchers and research staff must also be actively dispatched via these short-term programs (e.g., the American Association for Cancer Research/American Society of Clinical Oncology [ASCO] Methods in Clinical Cancer Research Workshop, the ASCO Leadership Development Program).

In developing further collaborative systems with the WHO, the Coalition for Epidemic Preparedness Innovations (CEPI), FIND, and other multilateral organizations and public-private partnerships, it is also necessary to encourage promote ongoing personnel exchanges with these organizations. Doing so will demonstrate Japan's presence in the event of an emergency. Although there have been some small-scale overseas training initiatives to this end, there has been little follow-up with trainees who have completed their training and returned to Japan. We should consider registering such human capital and conduct exchanges and follow-up activities as a strategy to build surge capacity for emergencies.

5. Methods for securing human capital

5.1 Methods for securing human capital in the event of an emergency

In the field of infectious diseases, it would be inefficient for the JIHS to employ the same quantity of personnel needed in an emergency during non-emergency times. Doing so would also hinder their ability to build up sufficient experience. At the same time, it is not efficient for the JIHS to develop such human capital from scratch.

Many excellent support personnel have been actively working in the clinical research core hospitals through AMED's Translational Research Program and Projects for Promotion of Clinical Research and Development.[5] Indeed, to date, the ARO Council's accreditation system has recognized 75 project managers and 65 study managers, as well as biostatisticians and data managers at each hub.[6] Some of this human capital can also be put to use in clinical trials conducted in cooperation with foreign institutions. For this reason, we must compile a list of the research support personnel at these clinical research core hospitals and national centers and place them on "standby." We can better prepare for emergencies by securing contracts with these institutions

[5] Information on AMED's translational research program is available (in Japanese) at https://www.amed.go.jp/program/list/16/01/012.html, and on its support for clinical R&D at https://www.amed.go.jp/program/list/16/01/004.html.

[6] Further information about the ARO Council's project manager/study manager accreditation system is available on its website (in Japanese) at https://aro.smartcore.jp/.

and facilitating cross-appointments in advance. This will create a system to consolidate the human capital needed for clinical trials in the event of the emergence of new infectious diseases. It would also be useful for personnel from the JIHS to be seconded to the clinical research core hospitals and national centers that have many products under development during non-emergency times so that they can gain practical experience.

5.2 Central organization for human capital

In order to develop and effectively deploy this human capital to achieve the intended objectives and advance the professional careers of specialists in each area, there needs to be a central organization responsible for identifying capable individuals, supporting their career progression, managing the pool of human capital, strategically planning activities that benefit participants, and implementing these activities in cooperation with the relevant stakeholders. In particular, in order for the JIHS to achieve its mission of preparing for the emergence of the next large-scale infectious disease, it is critical that it support the development and securing of human capital suitable for each level of roles, including the research leaders, the central support staff, and the local support staff. This underscores the importance of human capital development as a core objective of the JIHS in fulfilling its central support function.

5.3 Securing human capital with a diverse range of specializations

The researchers and ARO staff at the heart of clinical trials need to possess a diverse range of skills that go beyond clinical trial methodology and practical abilities to include an understanding of Japanese and foreign regulatory requirements and the ability to negotiate and communicate in English at a level that allows them to coordinate with foreign institutions. As it is difficult for a single researcher or ARO staff member to have all of these specializations, it is necessary to develop a system that brings together human capital with a diverse range of specializations to work as a team in conducting clinical trials. These teams should not only include Japanese staff but should actively promote the inclusion of foreign staff members as well. Furthermore, in addition to academic talent who are specialized in clinical trials, it is necessary to approach and secure human capital from diverse sources—including the pool of human capital with an interest in international activities (e.g., the Human Resource Strategy Center for Global Health), as well as people from pharmaceutical companies, CROs, and regulatory agencies. In particular, given that major pharmaceutical companies create pools of people with experience in managing foreign-led clinical trials that make use of foreign resources, seconding or re-employing such human capital will prove effective in the short term.

Moreover, Japan has very few biostatisticians working in AROs compared to the United States and Europe. To conduct clinical trials at an internationally accepted evidence level, Japan needs to continuously train biostatisticians. At present, the University of Tokyo and Kyoto University provide master's degree programs to train biostatisticians through the AMED's Support Program for Biostatisticians (AMED, 2024a). Nonetheless, it is necessary to look at providing mid- to

long-term post-master's training programs for biostatisticians (e.g., doctoral programs and experience in international activities), cooperating with national centers and universities to construct an ecosystem for training biostatisticians capable of playing an active role on the global stage.

5.4 Ensuring the mobility of human capital

To prevent the departments that conduct and support clinical trials from becoming siloed, it is important to ensure mobility among the central support personnel of the JIHS, the local support personnel of participating medical institutions in the network, and personnel handling patient care in clinical settings in order to facilitate the connection between research and clinical practice. Beyond just human capital mobility within hospitals, it is also necessary to promote mobility between hospitals and outside organizations, such as personnel exchanges with pharmaceutical companies and regulatory agencies, so that the views of diverse stakeholders can be incorporated into the organization's operations.

6. Establishing a strong foundation for activities (securing human capital by improving compensation, career paths, etc.)

6.1. Expansion of educational programs on clinical trials

First, to improve awareness in medical institutions of clinical trials, regular training should be conducted on the basics of clinical trials and on participation in clinical trials conducted at a global level for administrators and medical staff at medical institutions that conduct advanced clinical trials, such as the clinical research core hospitals national centers, and the advanced treatment hospitals. Such training will raise awareness of the importance of clinical trials in medical settings. The targets of this education should include the medical institutions that comprise the clinical trial network centered on the JIHS.

Second, for nurses and other medical staff who have direct contact with study participants and are at the forefront of data collection, OJT both within and outside the medical facility should be strengthened to provide basic knowledge about clinical trials and care for study participants. Doing so will raise awareness of clinical trials among not just researchers and the research support staff but also among medical staff in clinical settings, thereby improving the protection of study participants and the quality of the research.

Third, there are cases where researchers and ARO staff are familiar with domestic clinical trials but do not fully understand the importance of conducting international joint clinical trials in cooperation with foreign institutions. It is important to share the significance of international joint projects with researchers, central support staff, and local support staff and provide them with education to develop their ability to conduct clinical trials from a global perspective (i.e., global competence). Doing so will also strengthen their sense of being a member of the international community.

Fourth, from a long-term perspective, it is necessary to increase interest in careers related to clinical trials. To this end, clinical trials need to be added to student education and early post-graduate education for physicians and nurses, and subject matter related to clinical trials should be included in national exams and exams for medical specialists and for certified nurses and nurse specialists.

The strategic and continuous provision of such education requires more than the efforts of individual research institutions. The government must examine the possibility of developing an organization responsible for this.

6.2 Evaluation of contributions to clinical trials and systematization of careers

At present, the criteria for evaluating researchers focus on their publication history, regardless of whether they conduct basic or clinical research. The larger a clinical trial is, the harder it becomes to be listed as an author, but conversely, the results of such trials have greater significance to society. Therefore, core facilities, such as the clinical research core hospitals, must seek to include leadership of clinical trials and participation in or contribution to global clinical trials in their evaluation criteria in addition to publication history.

It is also necessary to establish a specialized career ladder and salary system for clinical trial support staff, including administrative staff, and in the case of medical professionals, to ensure that they are not disadvantaged in terms of the conventional medical professional career ladder but are instead evaluated according to their contribution to clinical trials. In addition, it is recommended that encouragement be given to having the contributions of frontline clinical staff who treat the patients participating in clinical trials be added to their evaluation criteria.

6.3 Incentivizing medical institutions for their contributions to the clinical trial network

For Japanese medical institutes, because clinical trials are not recognized as health care or treatment per se, the expenses involved in participating in the clinical trials network centered on the JIHS are not covered by the public health insurance. Only the portion of their activities that is patient care or treatment can be reimbursed. To maintain the network's ability to retain its members and play the role expected of it in an emergency, financial and non-financial incentives must be provided to medical institutions during non-emergency times according to the number of patients enrolled in clinical trials, their contribution to quality control, and their performance. Granting fair incentives will lead to the fair evaluation of staff's work related to clinical trials, as well as to the development of systems for conducting trials in these institutions.

6.4 Improving community literacy regarding pandemics

Preparedness for pandemics requires improved understanding and awareness among community members and local governments during non-emergency times. To ensure that community

residents and local governments recognize the importance of conducting clinical trials and the use of placebo-controlled trials, it is necessary to develop an educational system pertaining to these practices.

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Abbreviations

AMED	Japan Agency for Medical Research and Development
ARO	academic research organization
CRC	clinical research coordinator
CRO	contract research organization
MCM	medical countermeasures
OJT	on the job training
PMDA	Pharmaceuticals and Medical Devices Agency
SMO	site management organization
UHC	Universal Health Coverage
WHO	World Health Organization

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