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Evolving partnership: A National Center for Global Health and Medicine Resilient Training Model for clinical research professionals during the COVID-19 pandemic

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Abstract: The clinical trial industry has encountered challenging circumstances in which the increasing number of trials outpaces the number of trial specialists. For instance, there has been an unprecedented demand for clinical trials following the Covid-19 pandemic, which has worsened the global shortage of qualified personnel. It is therefore imperative to produce more qualified clinical trial professionals. An adaptive and collaborative training model was implemented by the National Center for Global Health and Medicine through the Department of International Trials. This aimed at building capacity among health workers in developing countries and providing them with the skills to be able to conduct all phases of the clinical trial from protocol design to publication of results. It also seeks to foster collaboration and partnership between local health workers and international experts. Since 2016, we have implemented a Japan-led training program, and since 2020, the COVID-19 pandemic has ushered in a shift from a single Train-the-trainer model (ToT) to a mixed model, the Evolving Partnership Training (ePT). In this model, we applied four different methods: train-the-trainer, needs-oriented training, open symposiums, and advanced learning. The total number of training participants increased exponentially from a total of 41 between 2016–2020 to 2,810 in 2021. Our experience has proven that despite the constraint of the pandemic, the ePT is a viable approach compared to a single method for providing quality training and increasing the number of participants.

Keywords: clinical trial professionals, evolving partnership training, National Center for Global Health and Medicine, training, train-the-trainer

The number and complexity of clinical trials has been increasing while the number of clinical trials professionals has not evolved in an equivalent way (*1*). Records from the WHO International Clinical Trials Registry Platform (ICTRP) that include observational and interventional studies compiled from different registries, had shown a continuous increase in number of registered studies all over the WHO regions since 1999 (*2*).

For example, on December19th, 2022 a total of 436,709 studies have been registered on *ClinicalTrials.gov* reporting a very steady increase with the advent of COVID-19 that accounts for 8,522 studies (*3*). In parallel, a global concern is raising the problem of shortage of clinical research professionals in all categories combined (*4,5*). This shortage was reported at 15% before the COVID-19 pandemic but has almost doubled to 29% during the post-pandemic period. Such a shortage may alter the proper functioning of clinical research operations (*6*).

According to the United States Food and Drug Administration (USFDA), only 3% of physicians and patients took part in a clinical trial that leads to new therapies and the majority were conducted at top academic institutions limiting the coverage of large proportion of the population (*7*). Only few professionals enter the clinical research industry with qualifications directly from the university (*1*). Medical school curricula allocate less time to educate students about the significance of biomedical research for better health care or to attract students to participate in biomedical research (8). In addition, the majority of clinicians do not receive enough exposure to research methods as part of their clinical development. Even fewer clinicians receive exposure to regulatory processes training, which is part of the core competency for clinicians who are involved in trials heading for regulatory approval (*1*).

Furthermore, the onset of the COVID-19 pandemic revealed to the world how weak health systems were and how little prepared both research communities and governments were for a possible health disaster. Moreover, we are not spared by the occurrence of a

pandemic X in the future (*9*).

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6-R2 (Good Clinical Practice) repeatedly mentions that each trial personnel "should be qualified by education, training and experience to perform tasks" (*10*). It is thus, of high interest to participate in the global efforts of filling the gap that is faced by the clinical research professional community.

Through the Department of International Trials, the National Center for Global Health and Medicine (NCGM), has been committed to improve access to healthcare by promoting international clinical research/ trials between Japan and partners in Asian and African countries.

From 2016 to 2020, we funded and implemented an annual training program using the training of trainers (ToT) model, during which topics related to clinical trials design and operations were discussed. Delegates from Democratic Republic of the Congo, Indonesia, Philippines, Thailand, Vietnam, and Japan joined a 2-week intensive short training program and participated as observer at the multiregional clinical trials seminar organized annually by the Japan Pharmaceutical and Medical Device Agency (PMDA). In order to evaluate the learning comprehension of the participants, pre-tests and post-tests were administered. In addition, all training materials were distributed to them, for their reference. Trainees were required to obtain a minimum of 80 % on the final evaluation test.

With the advent of the COVID-19 pandemic, global movements were restricted and face to face meetings of participants from different countries had become nearly impossible. In collaboration with past trainees, we then developed a new capacity building model which consisted of three pillars in addition to the ToT; first a needs-customized local training, second an advanced e-learning and third an international online symposium. We named the model as the evolving partnership training (ePT) model.

Regarding the needs-customized local training, contents were developed after consultation with past trainees and their supervisors to pin out training needs in their working environment. Each collaborating institution implemented trainings in their setting with a focus on particular topics related to their self-assessed local needs. Theses local trainings were conducted either by face to face, online or hybrid.

From the locally trained participants, 30 were selected to participate in the advanced e-learning program for principal investigators that included six main topics, pre-clinical studies, regulation for clinical trials, epidemiology, biostatistics for clinical research, data management and translational medicine. For the current training, we developed the content in collaboration with Chiba University and St Luke's University; Japanese experts were invited to provide the lectures.

As for the symposium, it is being carried out annually and involves key opinion leaders from various developed and developing countries who share their expertise on selected aspects of clinical trials. Figure 1 illustrates the mathematical model and components of the program.

In total, there were 41 trainees composed of physicians and statisticians who joined the ToT program in Tokyo from 2016 to 2020 – 6 in 2016, 8 in 2018, 14 in 2019, and 13 in 2020. In 2021, when the ePT was introduced, 2,810 professionals were trained locally in their respective countries by joining the local training, the e-learning and the online symposium as shown in the Figure 2.

The present training model, was a concept developed from the concept starting by a one-way ToT to a participative multilateral collaboration that could improve both the quality and the number of trained professionals. This illustrates that not only the funder gives his own orientation but also the learners by defining their needs, have active involvement in the implementation of the program. Participative collaboration in the program design is of great value because the training meets the learners self-assessed needs. We could observe an exponential increase in the number and quality of participants in the training program.

The ePT model is partially closer to the Analyze, Design, Develop, Implementation and Evaluate (ADDIE) (*11*) and to the ToT models (*12*). In fact, the first pillar of the ePT that consisted of the one-way training resulted in training of professionals able to train others in their individual settings. The second pillar that consisted of the local needs-customized training

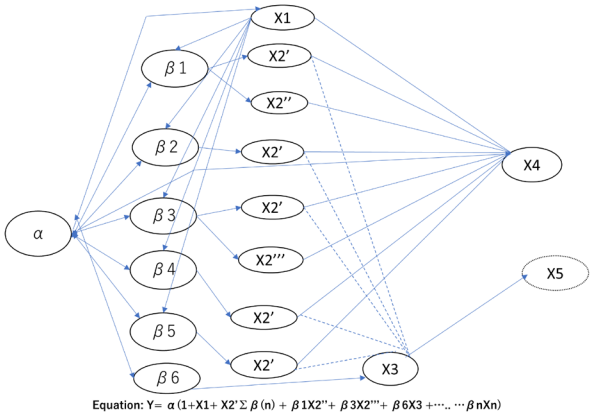

Figure 1. The evolving partnership training model (ePT). The ePT model includes the training of trainers, the need-customized, the advanced e-learning course and the open symposium. The needs-customized trainings were conducted either as: lecture type X2', webinar and conference X2'', or Discussion forum X2'''). α: Initiating Institution; β : Collaborative institution; X: Learning types; X1: training the trainers (ToT) course; X2: Needs – customized course (X2': lecture type; X2'': webinar, conference; X2''': Discussion forum); X3: Advanced e-learning course; X4: Open symposium; Y: number of trainees.

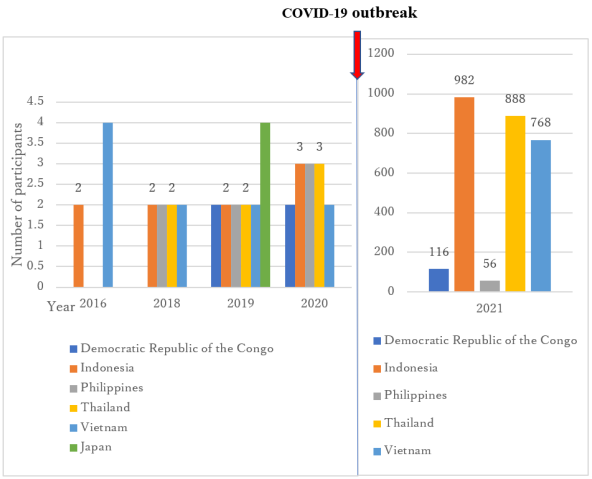

Figure 2. Distribution of training participants per country and per fiscal year. Participants from six countries joined the annual training program lead by the National Center for Global Health and Medicine. The number of participants has gradually increased over time with a remarkable increase in 2021 during the COVID-19 pandemic. *Note*: the scale is different in 2021.

program is similar to the ADDIE model in terms of analyzing the learner's needs and knowledge before designing and producing the content of the training.

For the ADDIE model, before starting to develop a course, you need to do the training needs assessment that would be the basis for the other steps of the implementation of the training and evaluation of the outcome. The difference is that in the ADDIE model the analyses are one-way from the trainers while in the ePT model, there are 2 layers of trainers that collegially develop the content of the training. However, the ePT model does not evaluate the outcome of the training as a whole but each of the ePT components were evaluated separately.

The ePT model is considered to be a mixed model that includes part of ADDIE and ToT, in addition to the multilateral involvement in the design of the content. The added value of the current training model is that the program is needs-oriented, cost-effective and involves partnership in design.

The limitation of the current model, is that we did not evaluate the outcome of the training as a whole in terms of the quality of trained professionals but one should assume that based on the content of the program and the motivation of learners, the program is worthwhile to have been implemented. Another limitation is that the content was not uniform for all the participants involved in the program, however, a needs-customized content is more valuable to solve real time issues faced by the learners to bring the solution to the locals by the locals. We assume that this component of the ePT motivates the participants to take ownership in finding solutions to their perceived problems in their research environment.

In conclusion, the current study has evidenced that despite the constraint of the COVID-19 pandemic, the ePT is a viable approach other than a single method for providing quality training and increasing the number of participants. This model should be one of the solutions, to participate in the global effort for capacity building of clinical trial professionals.

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