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International Collaboration Center for
Capacity Building in Infectious Disease R&D

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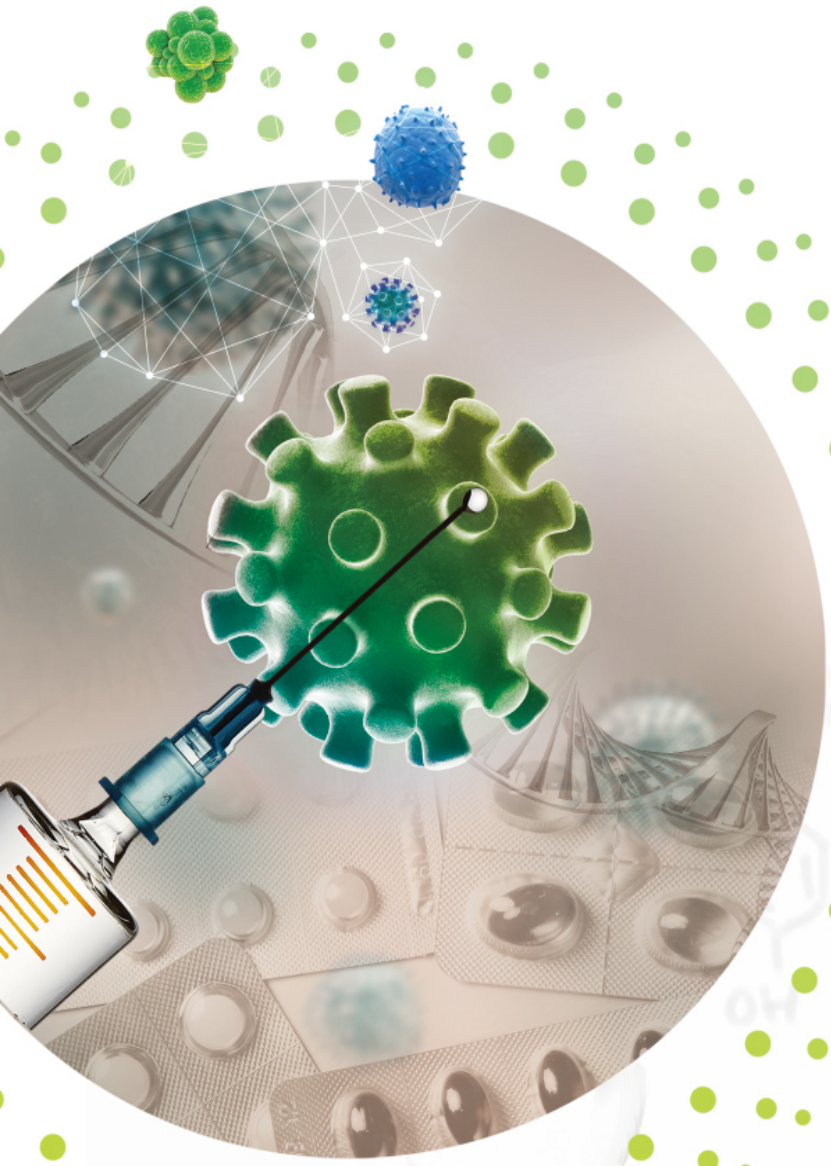

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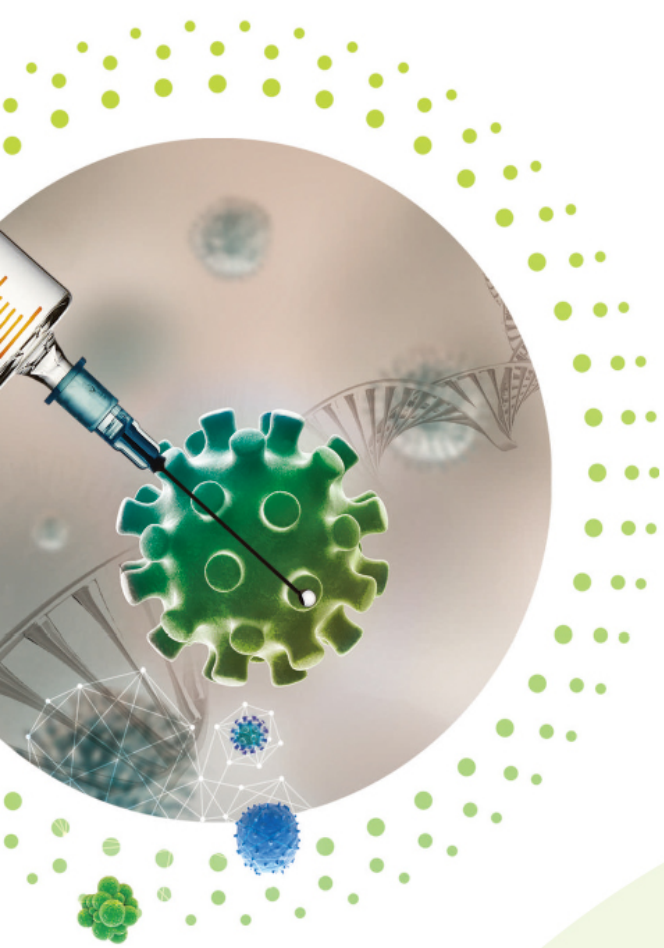
C³BIRD
International Collaboration Center for Capacity Building in Infectious Disease R&D

서울대학교
SEOUL NATIONAL UNIVERSITY

SNUH 서울대학교병원
감염병 관련 기초연구 및 임상시험 전문기관



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Greetings

C³BIRD Director **In-Jin Jang** MD, PhD

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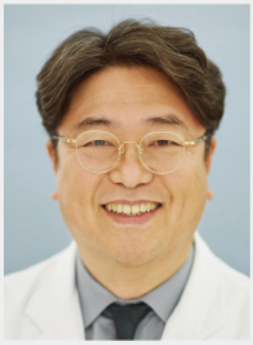


Hello, this is In-Jin Jang, director of C3BIRD project. Along with the globalization, the risk of the inflow of various infectious diseases has been rising continuously. Various researches have been conducted by not only the public but also the private sectors, but the lack of research sources in Korea are obstacles for these researches. To overcome these limitations, international collaboration in research with the foreign countries with high incidence of infectious diseases are crucial.

International Collaboration Center for Capacity Building in Infectious Disease R&D, C³BIRD, was built in 2017, and it aimed to set up the foundation for international collaborative research in infectious diseases. To accomplish the goals, C³BIRD opened a local research base center in Chiang Mai University (Thailand) to support collaborative clinical and basic researches. C3BIRD supported the designing and operating the local research base center, including appropriate training to the research staffs. Furthermore, C³BIRD established a total of three human resource exchange networks with National Institute of Hygiene and Epidemiology (Vietnam), University of Health Science (Laos), and University of Malaya (Malaysia). Based on C³BIRD's local research base center and researcher network, several pharmaceutical companies and medical devices companies are preparing clinical trials of vaccines and in-vitro diagnostics (IVDs).

Various activities of C³BIRD are anticipated to contribute towards potential risk reduction of the inflow of infectious diseases which are prone to cause economic loss and social unrest. In addition, promotion of the growth and activation of bio-pharmaceutical industry by successful development of new drugs including vaccine and diagnostic kits for infectious diseases are counted via the contribution of C³BIRD. C³BIRD aims to inform and communicate the latest news and activities related to international collaborative research on infectious diseases through this newsletter periodically. We look forward to your continued attention and supports.

01 Introduction of C³BIRD

(International Collaborative Research on Infectious Disease)

This study is part of the next generation project which is based on bio-social support among the bio-medical technology development projects. Basically, it aims to establish and to utilize the foundation for international collaborative research on risky infectious diseases which are possible to be flowed in Korea. According to data from the Korea Centers for Disease Control (CDC), the inflow of new and unknown infectious diseases into Korea is steadily increasing because of climate change, environmental destruction, increasing international exchanges, and etc. Thus, the needs for preventive research for early response to those infectious disease has been emerged. In addition, needs for research on infectious diseases in Korea has been emphasized because the demand for intermediation and clinical research increases.

It is necessary to have local base research center from abroad to cope with the demand for domestic research on infectious diseases. It also has been significant to establish efficient research system by this center, and the demand for treatments and vaccines related to infectious diseases has soared with the prevalence of these new infectious diseases. In practice, many said that a base of international collaborative research was needed for growth of the domestic pharmaceutical market and to overcome the high dependence of medicines of foreign pharmaceutical companies for infectious diseases.

Prof. Jang said “Through this project, we will establish a foundation for international collaborative research in the field of high-risk domestic infectious diseases. For this purpose, we want to conduct clinical and basic research at the global level with foreign institutions. We plan to establish an international cooperative human network with local institutions, and to set up overseas local research center to promote research on infectious diseases.” Concretely, it can be expected to activate customized research by operating domestic clinical and basic training courses for foreign researchers. Moreover, it can promote domestic research on infectious disease by infrastructure, technical, economical, and social achievements of this project.

02 Domestic and International Cooperative Network

Introduction of Domestic Cooperative Network in Infectious Diseases

KOREA UNIVERSITY

Korea University, as specialized institution for basic research on infectious diseases, is in charge of developing and operating training programs. In particular, these international courses on infectious diseases are for foreign researchers; therefore, this domestic cooperative network plays a role in building human network. In addition, it is responsible for establishing the foundation of collaborative research.

KOICID
(Korean International Cooperation for Infectious Diseases)

Since 2015, KOICID currently holds an international cooperative meeting (International Symposium for Cooperation on Infectious Diseases, ISCID) annually for foreign cooperative institutions, domestic companies, and related researchers. This international symposium is for them to meet and to discuss concerning international collaborative research. In addition, this domestic cooperative network imports and distributes human resources through the Korea International Biobank for Infectious Diseases, KOIBID. It also promotes mutual cooperation between government agencies, universities, research institute, and hospital internationally. Basically, it aims to develop the way to diagnosis, to treat, and to prevent infectious diseases. By extension, its fundamental purpose is to control the spread of infectious diseases between countries.

Introduction of International Cooperative Network in Infectious Diseases

Thailand

(Chiang Mai University, CMU)

Faculty of Medicine, CMU is the largest university in Northern Thailand and active in international cooperation. In practice, it operates collaborative research network for infectious diseases with institution in Myanmar, Laos, and Indonesia. And it focuses on the study of infectious diseases for the diagnosis, treatment, and prevention of diseases. It is also easy to conduct epidemiological investigation into infectious diseases since it has well-established epidemiological survey system. Moreover, it is possible to retain and to collect various high-qualified clinical samples, and is easy to exchange information related to infectious diseases with geographical advantage. The person in charge of C³BIRD project is Professor Prapan who is the head of C³BIRD research center.

Prapan Jutavijittum

Affiliation: Faculty of Medicine, Chiang Mai University
International Collaborative - C³BIRD Center
Position: Associate Professor,
Head of C³BIRD Center

Vietnam

(National Institute of Hygiene and Epidemiology, NIHE)

NIHE is an active organization in international cooperation. It has many types of viral pathogens, serum, and clinical samples, and its main fields of study are epidemiology, clinical microbiology, immunology, and molecular biology. Also, it conducts research to develop vaccines for Japanese Encephalitis, Hepatitis B and Cholera. This organization provides advices on national health care policies in Vietnam, and it reports type of Influenza which will be in vogue every year to CDC. The person in charge of C³BIRD project is Professor Dang Duc Anh who is the director of the NIHE.

Dang Duc Anh

Affiliation: National Institute of Hygiene and Epidemiology
Position: Director

Laos

(Ministry of Health, Department of Basic Health Science, UHS)

UHS, Lao PDR has many samples which are related to subtropical virus in Southeast Asia. Furthermore, it conducts an international collaborative research through consultation, regulation, and operation on clinical research facilities. The person in charge of C³BIRD project is Professor Bounthome who is vice president of the UHS, Lao PDR

Bounthome Samountry

Affiliation University of Health Science
Position Vice President

Malaysia

(University of Malaya, UM)

UM is a new local human resources exchange center which conducts clinical research itself actively. It is a cooperative institution that is expected to collect and to retain clinical samples for various infectious diseases. The person in charge of C³BIRD project is professor Adeeba who is dean of the Faculty of Medicine, UM.

Adeeba Kamarulzaman

Affiliation Faculty of Medicine, University of Malaya
Position Dean

03 Customized Research and Local Base Research Center

Current Status of Customized Infectious Disease Research

At this time, the main purpose related to the customized research of infectious disease is planning for clinical research through a local base research center. In addition, the goal of this research is to accelerate the development of infectious disease diagnosis kit, vaccines, and medications towards local markets. Factually, contract research organization conducted the survey of demand for basic and clinical research concerning infectious diseases from foreign countries with subject to domestic demand such as academic, pharmaceutical, diagnostic device industry, etc. Additionally, researchers from overseas local base and people from human resources exchange centers were also investigated. Based on those results, strategies for development and support program of customized research can be established. In other words, it can establish a cooperative system with CRO, academia, and pharmaceutical industries. Thus, it can be expected to promote customized research on infectious disease and to reduce costs.

Kogene Biotech

Kogene Biotech conducted collaborative meetings and on-site visiting. This company conducted pilot study with diagnosis instruments such as IKV, DENV, CHIKV Multiplex Real-Time PCT Kit & DENV Serotype Real-Time PCR Kit developed by using samples from Thailand. It is currently preparing a IDE submission to the Ministry of Food and Drug Safety, MFDS.

CJ Healthcare & LG Chem.

Both CJ Healthcare and LG Chem. held own meetings of researchers for cooperation including collaborative research on vaccine development.

CliPS

CliPS actually visited CMU and NIHE to discuss international cooperation. This company also concluded clinical research MOU with CMU. Currently, the PI for pediatric clinical study of BCG vaccine was selected, and it finalized the development of clinical study protocol.

ADM Korea

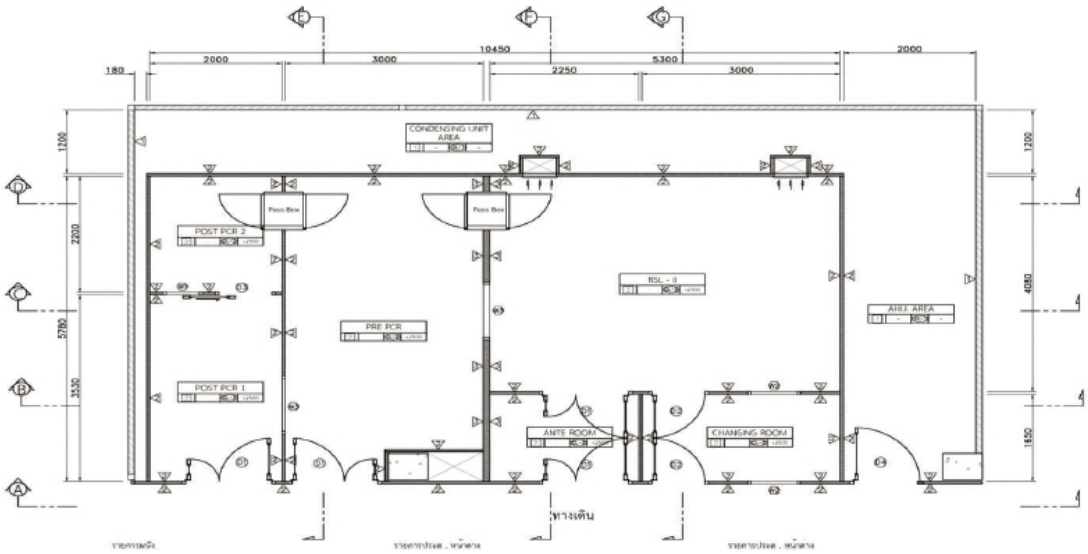
ADM Korea hired local employees in Thailand. It is expected that it will act as a bridge for collaborative research with Korean pharmaceutical and medical device companies in the future.

Introduction of Local Base Research Center (C³BIRD - Thailand)

For a long time, Thailand has actually conducted various collaborative researches with many research institutes in the field of tropical medicine and infectious diseases. Thus, Thai researchers have precise knowledge of many infectious diseases, and they are linked to many institutions directly. Studies conducted in Thailand have higher quality and influence compared to those conducted in Indochina Peninsula countries such as Laos, Vietnam, Myanmar, and Cambodia. Also, as stated above, researchers from Thailand have long experience in conducting collaborative researches with other organizations; therefore, remarkable success is expected in this study. Tropical diseases are common in Southeast Asian countries, and these are preferred area of research at Faculty of Medicine, CMU. In particular, research conducted by the undergraduate department of medical school deals with virus, bacteria, and parasite infections which affect not only the local residents but also global population.

<C³BIRD Local Base Research Center in CMU>

On February 26th 2018, International Collaborative C³BIRD Center opened under Faculty of Medicine, CMU. This research center consists of 2 dry lab rooms, 1 wet lab, 1 Biobank, 1 conference room, and 1 office. Among these facilities above, some of the lab and office space are currently used by CROs from Korea and researchers. Moreover, as of April 2020, construction and certification of Bio-Safety Level 2+ laboratory have been completed, so local laboratories and clinical trial centers are also being operated and supported. C³BIRD'S local hub research center as the basic infrastructure



<C³BIRD - Blueprint of biosafety Level 2+ Laboratory Room in CMU>

for the control of infectious diseases through multi-national cooperation can be used for collaborative research in the future. Various achievements are also expected with this local research center. Furthermore, there are three expected achievements through this local hub center. Firstly, economic outcome can be expected by connecting with local institution to induce reducing research costs. Secondly, social and economic results can be acquired by developing and operating customized clinical research program. Finally, technical achievement can be anticipated by developing and operating SOP of collaborative research network. Development of clinical trial plan form is also being planned at international level.

<C³BIRD - Biosafety Level 2+ Laboratory Room in CMU>

04 Training for Foreign Researchers

Visiting Training for Foreign Researchers in Korea

Domestic Training for foreign researchers aims to improve their capabilities to conduct international cooperative research through their clinical and basic research training. During the first phase of this project (2017-2020, 1st-3rd years), a total of 7 basic training courses were opened. Those basic training course are as follows: Basic Good Clinical Practice, Basic Good Laboratory Practice, Clinical Trial & Ethics, Bioinformatics, Biostatistics, Immunology Work, Research and Development. Even now, curriculums are constantly developing and improving with the demand of foreign researchers. In the case of basic training in Korea, by country, a total of 156 trainees including 45 from Thailand, 50 from Vietnam, 56 from Laos, and 5 from Malaysia completed courses.

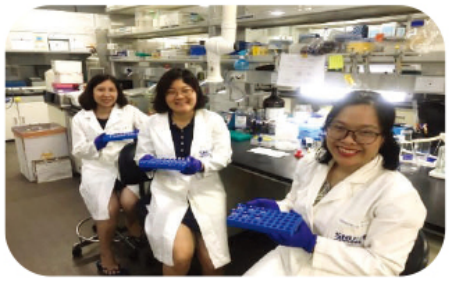
Basic Courses for Foreign Researchers and Number of Completed Trainees

- Basic Good Clinical Practice
- Basic Good Laboratory Practice
- Clinical Trial & Ethics
- Bioinformatics
- Biostatistics
- Immunology Work
- Research and Development

Country	Number of Trainees
Thailand	45
Vietnam	50
Laos	56
Malaysia	5
Total Number of Trainees: 156	

<Topic of Basic Course for Foreign Researchers>

Course Name	Course Topic
Basic GCP	Basic Training and Practice on Clinical Trials in general
Basic GLP	Basic Training and Analytical Practice for Laboratory Studies
Clinical Trial & Ethics	Design, Procedures, and Precautions on New Drug Development Stages and Clinical Trial Research / Management Plan about Adverse Reaction during Clinical Trials / Training related to the Preparation and Compliance of SOP in Clinical Trials / Training on Ethical and Legal Training
Bioinformatics	Training on Utilization Plan for Bioinformatics
Biostatistics	Basic Statistical Training required from Clinical Trial Planning to Completion Report and Practice with Practical Studies
Immunology Work	Practice on Immunology-based Experimental Techniques and Research Methods
Research and Development	Training on Clinical Trials as a whole, The Way to Write Budget for Research Planning, Training on Research Results and Strategies for communicating with Pharmaceutical Companies about New Drug Development



During the first phase of this project (2017-2020, 1st-3rd years), 6 additional advanced training courses were opened in total, and those were based on training feedback and demands from trainees who were all foreign researchers. Those advanced training courses are as follows: Advanced GCP, Institutional Review Board, Advanced Statistics, Advanced Immunology, Metabolomics - Biomarkers, IVI's International Vaccinology. In the case of advanced visiting training in Korea, total of 51 trainees including 27 from Thailand, 20 from Vietnam, and 4 from Laos completed one of these advanced courses. To sum up, from the 1st year to the 3rd year (Stage 1), a total of 207 foreign researchers visited Korea to complete basic and advanced courses as part of C³BIRD project.

Advanced Courses for Foreign Researchers and Number of Completed Trainees

- Advanced GCP
- Institutional Review Board
- Advanced Statistics
- Advanced Immunology
- Metabolomics / Biomarkers
- IVI's International Vaccinology

Country	Number of Trainees
Thailand	27
Vietnam	20
Laos	4
Total Number of Trainees: 51	

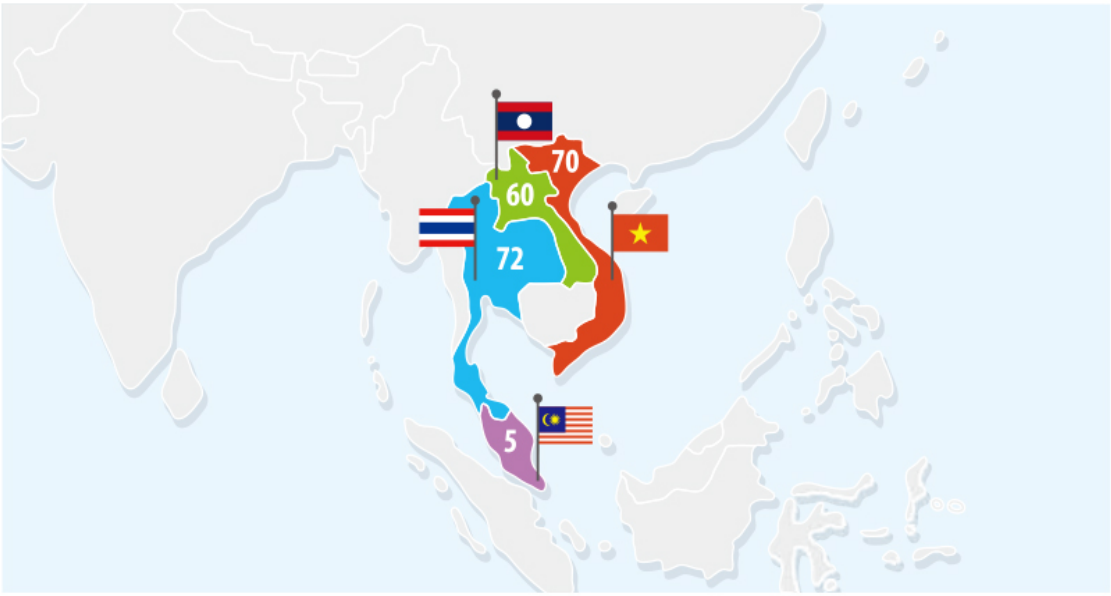
<Topic of Advanced Course for Foreign Researchers>

Course Name	Course Topic
Advanced GCP	Intensive Training and Practice on Clinical Trials in general
Institutional Review Board (IRB)	Basic Training and Practice on Institutional Review Board
Advanced Statistics	Intensive Training and Practice on Extracting and Analyzing Data / Method to Interpret Results
Advanced Immunology	Advanced Course on Immunological Experimental Techniques and Research Methods
Metabolomics / Biomarkers	Basic Training on Metabolomics and Biomarkers
IVI's International Vaccinology (Commissioned)	Comprehensive Overview of Vaccine Development, Review of Epidemiology and Immunology, Training on discovery, development, and dissemination of vaccines.

From the second phase of this project (2020-2021, 1st-2nd years), it aims to reinforce network on international collaborative research and to advance manpower training program. To be specific, during this period, the main points are the advancement of domestic clinical trials and that of basic research training courses for foreign researchers. Fundamentally, it is expected to have invitational training in Korea for more than 40 researchers from more than 3 countries. In detail, training and practice on the operation of laboratories and that of clinical research centers which are related to infectious diseases are planned. Training including practice on the operation of biological safety facility is one of the most significant courses during the second phase of this project.

–Training Completion (Thailand, Vietnam, Laos, Malaysia)

Total: 207 Trainees (Training in Korea)



Country	Basic Course	Advanced Course	Total
Thailand	45	27	72
Vietnam	50	20	70
Laos	56	4	60
Malaysia	5	-	5
Total Number of Trainees: 207			

<Total Number of Trainees who completed Basic and Advanced courses for Foreign Researchers in Korea>

Training for Staffs from Local Research Center (C³BIRD Center, Thailand)

In the case of on-site visiting training, advanced research and training courses were operated including local researchers who completed domestic trainings from Stage 1(From 1st year to 3rd year) in Korea. Particularly, this on-site visiting training was conducted for staffs from local research center. In total, 117 researchers from this C³BIRD center in Thailand completed this training, 28 in the first year, 34 in the second year, and 55 in the third year.

From the Stage 2(second phase of this project), BSL+2 experimental facility will be operated actively; therefore, development assistance and training concerning SOP for this facility will be provided. Especially, from the second phase of first year (2020), on site visiting is planned to promote their clinical research capabilities. In the second phase of the second year (2021), local visiting training is arranged to utilize and to complete clinical research capacities. Furthermore, it aims to support and to advance other human resource exchange centers: Vietnam, Laos, and Malaysia. Same as local research center in Thailand, it plans to run advanced research and training course for local researchers who completed training in Korea from the human resources exchange center.

–Training Completion (Thailand - Chiang Mai University)

Total: 117 Trainees (Training in Local Research Center)

1st Year (28 Trainees)

2nd Year (34 Trainees)

3rd Year (55 Trainees)

<Training for Staffs from Local Research Center (Thailand)>

05 Plan for Stage 2 (2020-2021)

"Establishing and Utilizing the Base for International Collaborative Research on High-Risk Infectious Disease (Local Laboratory, Human Resource Training)"

	Stage 1 (2017~2019)	Stage 2 (2020~2021)
Purpose	Establish Local Base Research Center and Development and Operation of Program	Advance Network and Program for International Collaborative Research
Contents	• Construct local research and human resources exchange center • Training for foreign researchers and international symposium • Obtain infectious substances & clinical samples (preliminary)	• Develop the level of collaborative research (local center) • Expand and reinforce the human resources exchange network • Conduct the customized study of infectious diseases

Outcome and Application — Indicator and Objective: generate, spread, and utilize results

Infrastructure	Local Base Research Center (Thailand); Human Resources Exchange Center (Vietnam, Laos, Malaysia)
Technology	Develop and Operate Human Resources Program (Include Clinical SOP)
Economy	Reduce Research Expenses (Customized Infectious Disease Control)
Social	Improve Research Capabilities (Training of Human Resources – in Foreign Countries ≥ 20 people / year) (in Foreign Countries Total ≥ 200 people / 5 years)

Expected Efficacy — Acceleration of domestic infectious disease control research through international collaborative research

Advance Operation and Extend Usage of Local Base Research Center (Thailand)

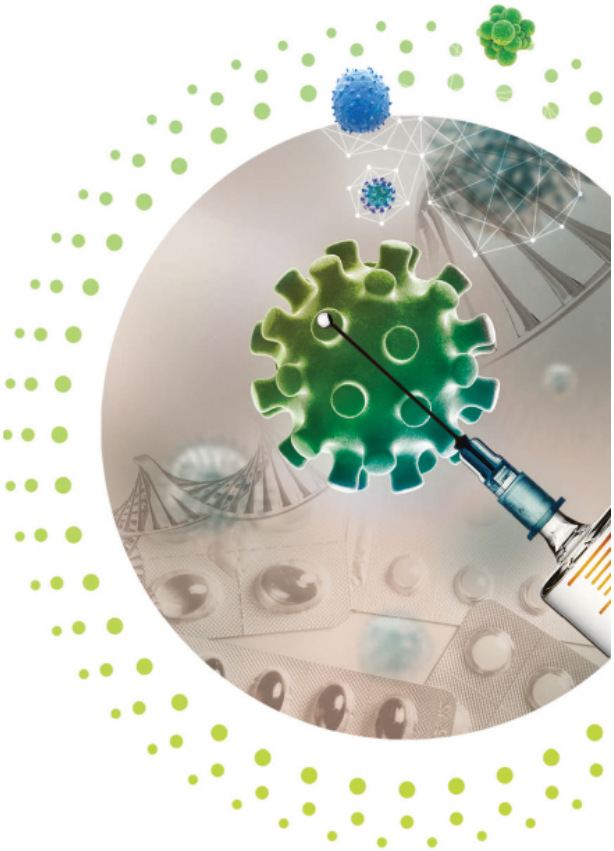
- BSL-2+ Laboratory Support and Operation - enhancement of research capacity
- Clinical and Basic Research Operation and SOP Application and Training
- Advance the Facilities, Equipment, Manpower from Local Base Research Center
- Practical Use of Local Research Center and Identify the demand of Research on overseas infectious disease - Plan for International Cooperative Research
- Upgrade Visiting Training Program
- Promote Local Base Research Center through International Symposium

Expand and Reinforce the Human Resource Exchange Networks

- Expand and Reinforce the Human Resource Exchange Networks
- Conduct Domestic Invitational Training and On-Site Visiting Training
- Advance and Operational Support for Human Resource Exchange Center (Vietnam, Laos, Malaysia)
- Expand International Cooperative Network by exploring New Human Resource Exchange Center (Myanmar, Mongolia, Cambodia, etc.)
- Advance and Operate Clinical and Basic Research Training Courses for Foreign Researchers in Korea
- Enhance Domestic and International Networks by hosting International Symposium

Conduct and Support the Customized Study of Infectious Diseases

- Conduct and Support the Customized Study of Infectious Diseases
- Initiate the Clinical Trials with Vaccines
- Proceed International Collaborative Research with Domestic Researchers
- Promote Cooperation and Clinical Research with Domestic Pharmaceutical companies and Medical Devices firms, and CROs
- Progress Research and Development for Vaccines, Medications, and Diagnostic Kits through Local Base Research Center
- Promote International Collaborative Research to control Infectious Diseases through Multi-National Cooperation
- Conduct and Progress various Customized Research



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