

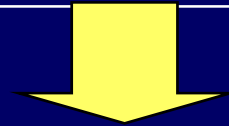
**Launch
of a new Diploma, MSc & PhD programme
in Research & Development
of Products to meet Public Health Needs**

**Kenji Hirayama
Institute of Tropical Medicine
Nagasaki University**

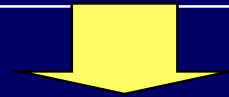
Win Gutterrage, Janis Lazdins, Juntra Karbwang (WHO/TDR, Switzerland), Jin Hong Hu (Second Military Medical Univ, China), Kesara Na-Bangchang (Thammasat Univ, Thailand), Chitr Sitthi-amorn (Chulalongkorn Univ, Thailand), Kiichiro Tsutani (Univ of Tokyo, Japan), Ivan Valez (Univ of Antioquia, Colombia),

Why necessary?

Drug/vaccine/diagnostics Research & Development for the developing countries Should be promoted more under international settings (10/90 gap, Neglected Disease)



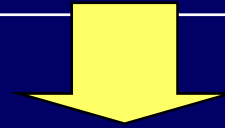
More human resources are needed



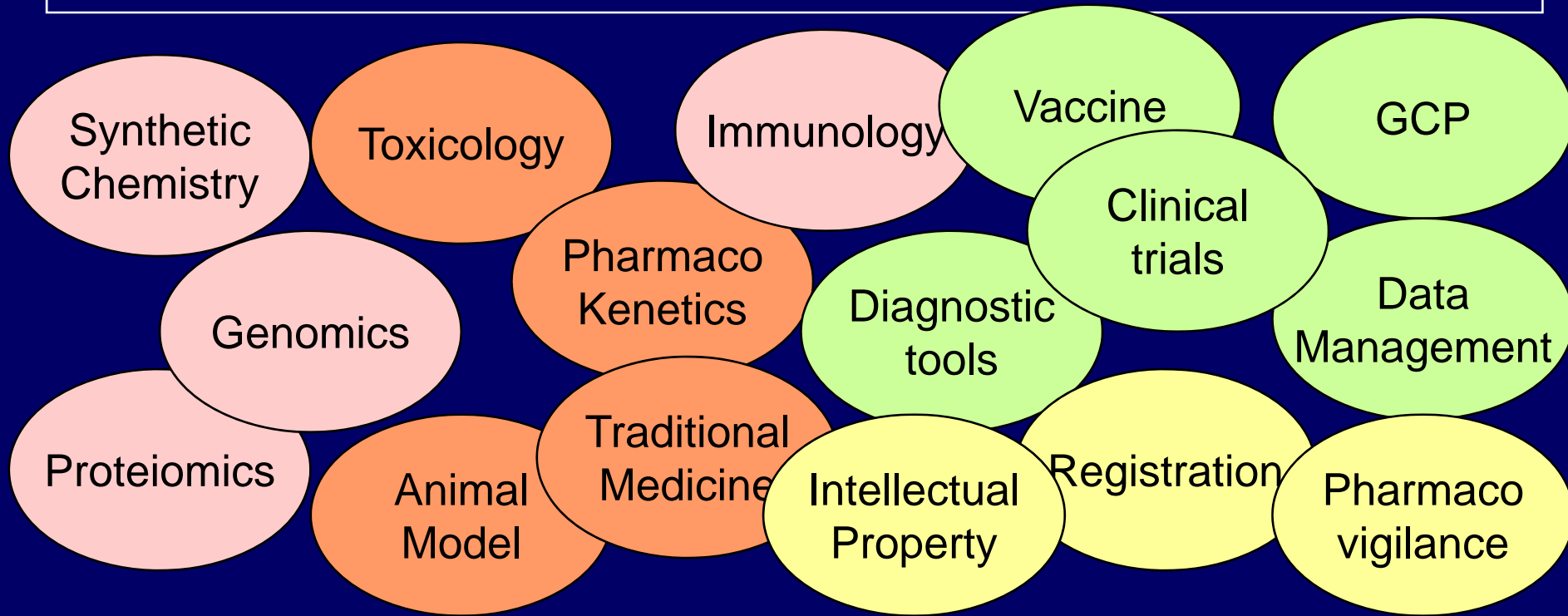
Diploma, MSc & PhD programme in Research & Development of Products to meet Public Health Needs

Who can teach whom?

There is no single university who can cover all the areas of Product development.



World-wide search for the best teachers



International Collaborative Efforts!

**Postgraduate Education
Cooperated by the network of
International Universities**

Nagasaki University, The Univ. of Tokyo (Japan)

Thammasat Univ., Chulalongkorn Univ.

Mahidol Univ. (Thailand)

Second Military Medical University (China)

Univ. of Antioquia (Colombia)

**Supported by
WHO/TDR and
Pharmaceutical Society of Japan**

Final Picture of the Programme

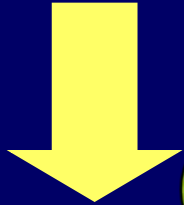
Seven Universities

Students

Diploma Course
on R&D of Products
to Meet Public Health
Needs

Initiation Course to
Show all the processes
Of Product
development

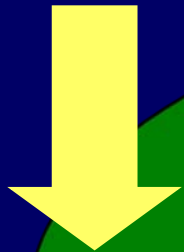
Step 1



Specialty selection and
initial training to get
Master degree

Registry of
Variety of
Specialties

Step 2



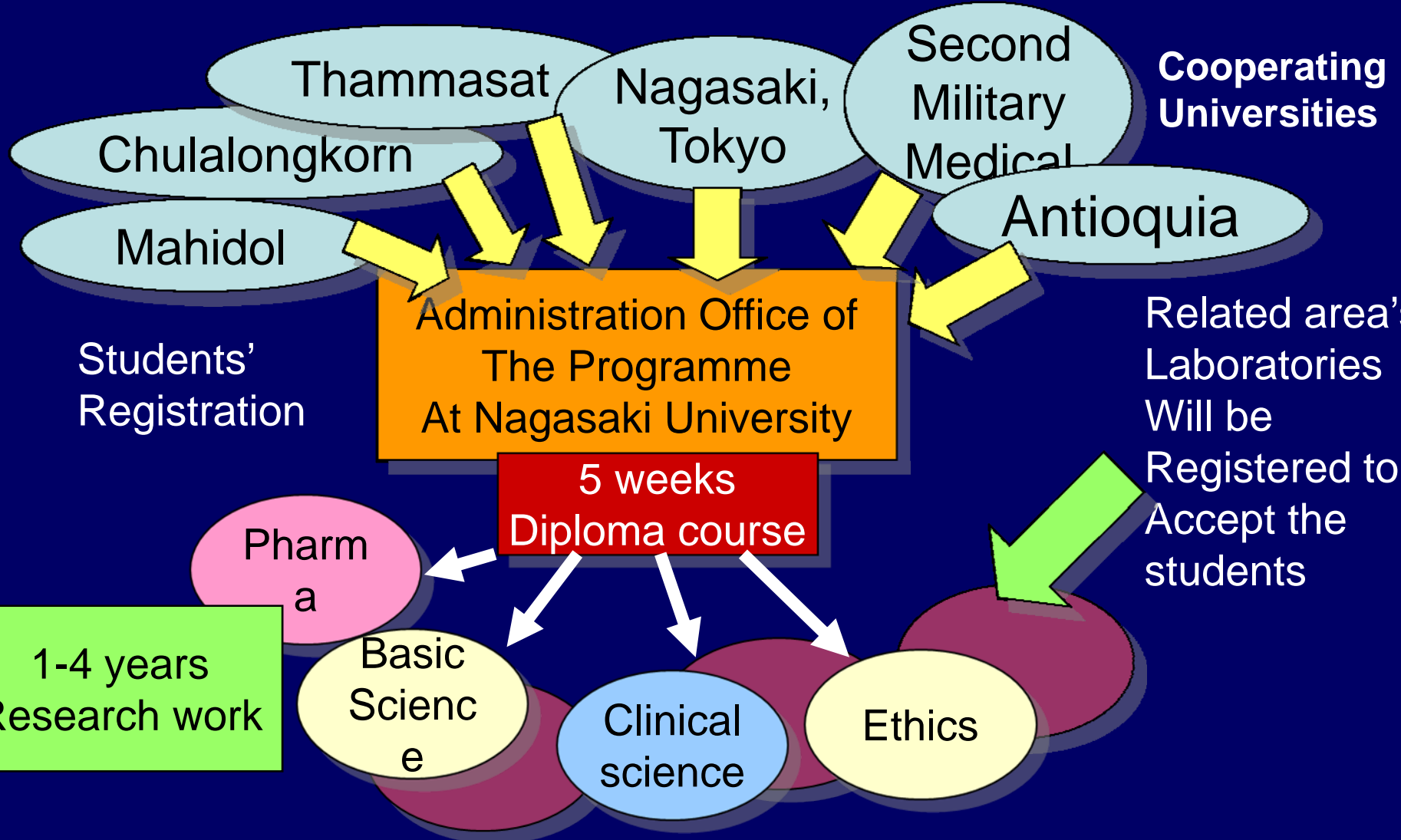
Step 3

PhD course
More intensive research training
and Thesis work
Given the PhD from
registered University

Professionals

Researchers

Diploma, MSc & PhD programme in Research & Development of Products to meet Public Health Needs



MSc, PhD on PD Given by the original university

**Diploma Course
on Research & Development of Products
to Meet Public Health Needs**

Sponsored by Nagasaki University

*in cooperation with Thammasat University, Chulalongkorn University,
China Second Military Medical University, Antioquia University
and The Graduate School of Pharmaceutical Sciences of The University
of Tokyo*

*in collaboration with WHO/TDR
and The Pharmaceutical Society of Japan (PSJ)*

*Nagasaki University, Japan
October 2 - November 8, 2006*

Module 1 : Orientation

- Key medical and public health issues, and the need for new products
- Discovery research and product development Stakeholders

Module 2: Drug Development

- Drug Discovery
- Chemical Manufacturing and Control
- Preclinical and Toxicology

Module 3: Vaccine Development

- Vaccine Discovery
- Vaccine Development

Module 4: Diagnostic Development

Module 5: Good Clinical Practice (GCP)

- GMP, GLP, GCP, ICH
- Ethical Review and Guideline
- Field Trip to Factory

Module 6: Clinical Data Management

Module 7: Post Registration Activities

- Pharmacovigilance, PPP, Intelligent Property

Product R&D Diploma Course 2006

延: 64 講師

Oct 2 ⁽¹⁴⁾

Oct 9 ⁽¹⁰⁾

Oct 16 ⁽¹²⁾

Oct 23 ⁽⁷⁾

Oct 30 ⁽⁹⁾

Nov 6 ⁽¹²⁾

Mon	2 齋藤 ✓ 平山 ✓ JANIS (a) ✓ 内田 ✓ modul 1 ①	9 小野 ✓ 伊東 ✓ 黒沢 ✓ 2-6	16 Jeeyaseelen ✓ ①	23 堀内 ✓ Geneva 3-4	30 Cristina ✓ Vichai ✓ 平山 ✓ Module 5 5-1	6 Chacrin ✓ Loui Wang ✓ Rajagban ✓ Sankae Joo ✓ Kosara ✓ module 6 -
Tue	3 野呂 ✓ 太田尚 ✓ modul 2 14:00? ✓ 16:00 ✓	10 Wongwivat ✓ Soisawan ✓ 2-7 ①	17 川上 ✓ Juntra ✓ 2-13	24 堀内 ✓ Geneva 3-5	31 Cristina ✓ (Juntra) Allan ✓ Johansen ✓ Dinner 5-2	7 Chitr ✓ Yupin ✓ 木村和子 ✓ 津谷 高橋 ✓ module 7 7-1
Wed	4 芥本 ✓ 片峰 ✓ 木下 ✓ Prasit ✓ 北 ✓ 2-2	11 Wongwivat ✓ Soisawan ✓ 2-8	18 津谷 ✓ Luping Qin ✓ 新井 ✓ ①	25 狩野 ✓ 平山 ✓ 上田 ✓ Pete Chong ✓ Geneva 3-6	Nov 1 Johansen ✓ 平山 ✓ Cristina ✓ 柴崎 ✓ 5-3	8 Chitr ✓ Janis ✓ Yupin ✓ 山根裕子 ✓ 7-2
Thu	5 大澤 ✓ 2-3	12 動物施設 大沢 ✓ 谷口 ✓ 2-9	19 Howard ✓ 平山 ✓ modul 3 3-1	26 野呂 ✓ 吉野 ✓ 3-7	2 佐藤 (化血研) ✓ 能本 ✓ 5-4	
Fri	6 畑山 ✓ 甲斐 ✓ 長岡 ✓ Supomchai ✓ ① 2-4	13 谷口 ✓ Wongwivat ✓ 2-10	20 Howard ✓ 3-2	27 佐木 ✓ modul 4 4-1	③	
Sat	7 長岡 ✓ 2-5	14 野中 ✓ 笠原 ✓ Liou ✓ 2-11	21 Pan ✓ 江原 ✓ 森田 ✓ 新川 ✓ 3-3	28	4	
Su	8 平山 樹 北 7x ✓ 15	15	22 Geneva	29	5 !! 外国人 ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ ⑪ ⑫	

Course Orientation

President, Prof. Dr. Hiroshi Saitoh, Nagasaki University, Japan
Professor Dr. Kenji Hirayama, Director of the course, Nagasaki University, Japan
Dr. Janis Lazdins, WHO/TDR, Geneva
Prof. Dr. Eiji Uchida, Showa University, Tokyo, Japan

Drug Development

Mr. Nobuhiro Noro, GSK, Japan
Dr. Hisashi Ohta, Tsukuba Institute Merck Banyu
Dr. Prof. Tadashi Yoshimoto, Nagasaki University
Prof. Shigeru Katamine, Nagasaki University, Na
Assoc. Prof. Dr. Prasit Palithapolkarnpim, BIOTE
Dr. Mitsuyoshi Kinoshita, Otsuka pharmaceutical
Prof. Dr. Kiyoshi Kita, The University of Tokyo, J
Dr. Kenichi Osawa, Merck Banyu Pharma, Japan
Prof. Dr. Susumi Hatakeyama, Nagasaki Univers
Prof. Dr. Masaaki Kai, Nagasaki University, Japa
Prof. Dr. Hiroaki Nagaoka, Nagasaki Internationa
Assoc. Prof. Supornchai Matangkasombat, Mahidol
Dr. Shunsuke Ono, University of Tokyo, Japan
Dr. Hiroyuki Itoh, Astellas Pharma Inc, Japan
Dr. Tsutomu Kurosawa, Osaka University, Japan
Assoc. Prof. Dr. Wongwiwat Tassaneeyakul, Kon Ka
Dr. Soisanwan Satarug, University of Queensland, Aus
Dr. Kazuki Osawa, Nagasaki University, Japan
Dr. Tadaaki Taniguchi, Japanese Association of Pharmac
Medicine (JAPHMED), Merck Banyu Pharma, Japan
Dr. Kenji Nonaka, Japanese Association of Pharmaceutical Medic
(JAPHMED), Merck Banyu Pharma, Japan
Dr. Kimihiro Kasamo, Japanese Association of Pharmaceutical
Medicine(JAPHMED), Merck Banyu Pharma, Japan
Dr. Shyh-Yuh Liou, Japan Section GlaxoSmithKline, Japan
Prof. Dr. L. Jeyaseelan, Christian Medical University, Vellor, India
Prof. Dr. Koji Kawakami, Kyoto University, Kyoto, Japan
Prof. Dr. Juntra Karbwang, WHO/TDR, Switzerland
Professor Dr. Kiichiro Tsutani, University of Tokyo, Japan
Dr. Ichiro Arai, Manager, R&D Strategy Dept. Tsumura & Co.
Professor Dr. Luping Qin, China

More than 60 Professors and Lecturers of Expertise have come from all over the world



Vaccine Development

Dr. Howard Engers, AHARI, Ethiopia
Prof. Dr. Kenji Hirayama, Nagasaki University, Japan
Prof. Dr. Weiqing Pan, Second Military Medical University, China
Dr. Masahiko Ehara, Nagasaki University, Japan
Prof. Dr. Kouichi Morita, Nagasaki University, Japan
Dr. Takeshi Arakawa, Ryukyu University, Japan
Dr. Kiyoshi Horiuchi, GlaxoSmithKline KK, Tokyo, Japan
Dr. Shigeyuki Kano, International Medical Center of Japan, Tokyo
Dr. Pele Chong, Taiwan
Dr. Shigeharu Ueda, The Research Foundation for Microbial Diseases of Osaka University (BIKEN), Japan
Dr. Nobuhiro Noro, GlaxoSmithKline KK, Tokyo, Japan
Dr. Yasushi Yoshino, Dr. Masaru Iwasaki, GlaxoSmithKline KK, Tokyo, Japan
Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan

GCP Data Management

Dr. Vichai Chokevivat, FERCAP, Thailand
Prof. Dr. Cristina Torres, FERCAP, Thailand
Prof. Dr. Kenji Hirayama, Nagasaki University, Japan
Dr. Allan Johansen, Roche Products Pty limited, Australia
Prof. Dr. Masakatsu Shibasaki, The University of Tokyo, Japan
Dr. Tetsuro Satoh, Kaketsuken, Kumamoto, Japan
Dr. Charerin Na-Bangchang, TU-CDMC, Thailand
Dr. Rui Wang, SMMC-CDMC, China
Dr. Arunachalam Rajagopal, CMC-CDMC, India
Dr. Jose Fernando Florez Arango, CMC-CDMC, Colombia
Dr. Sangkae Chamnanvanakij, TU-CDMC, Thailand

Post-registration Activities

Prof. Dr. Chitr Sitthi-amorn, Chulalongkorn University, Thailand
Prof. Dr. Kazuko Kimura, Kanazawa University, Japan
Dr. Kihito Takahashi, JAPHMED, Merck Banyu Pharma
Prof. Dr. Yupin, FDA, Thailand Prof. Dr. Kiichiro Tsutani, University of Tokyo
Dr. Janis Lazdins, TDR/WHO, Geneva Prof. Dr. Yupin, FDA, Thailand
Prof. Dr. Chitr Sitthi-amorn, Chulalongkorn University, Thailand
Prof. Dr. Hiroko Yamane, Graduate Institute for Policy Studies, Japan
Prof. Dr. Juntra Karbwang, WHO/TDR, Geneva
Prof. Dr. Kenji Hirayama, Course Director, ITM, Nagasaki University



Opening Ceremony October 2, 2006

President Saito



Janis
WHO/TDR



Uchida
Showa Univ



Noro
GSK Japan

Module 1 Introduction

Module 2. Drug Discovery



Katamine Prof



Kinoshita
Otsuka

Kita Prof
Univ Tokyo



Ohta Merck



Prasit
Biotech
BKK



Noro GSK





Intellectual Property
Osawa, Merck Banyu

Elaine Chen Taiwan



Tepanata, Chanida
Orapin from Thailand



Yoshimoto, Kai
Hatakeyama Profs
Nagasaki Univ

Song, Zhang, Wang
Military Medical Univ
China





Supornchai
Mahidol

Nagaoka
CMC



Katalina, Jerver from
Colombia



Itoh
Astellas



Ono
Univ Tkyo

Regulatory And Animal model

Kurosawa
Osaka Univ

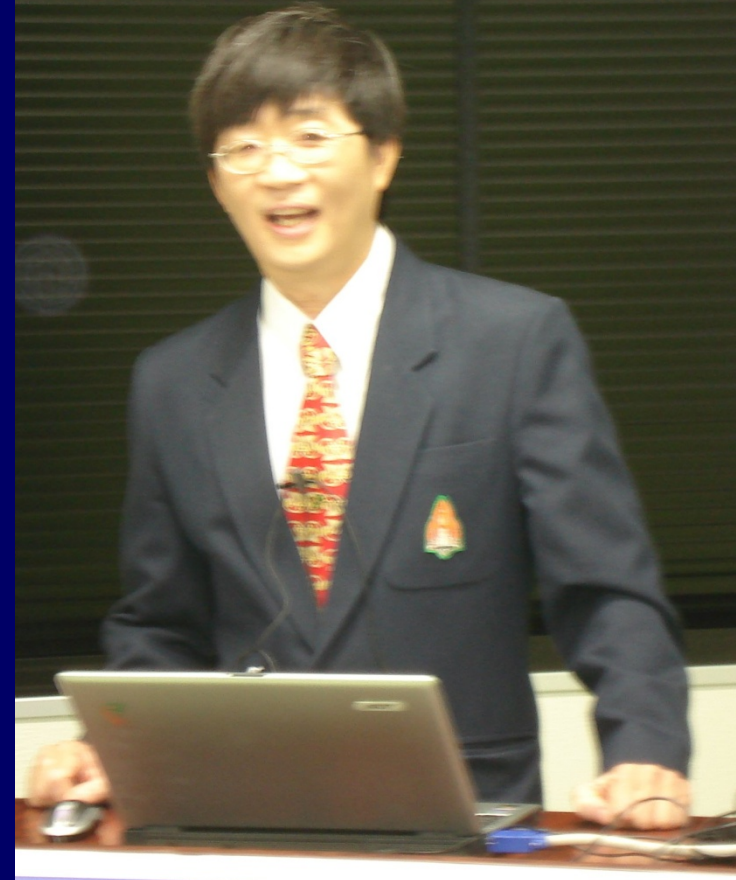


Preclinical



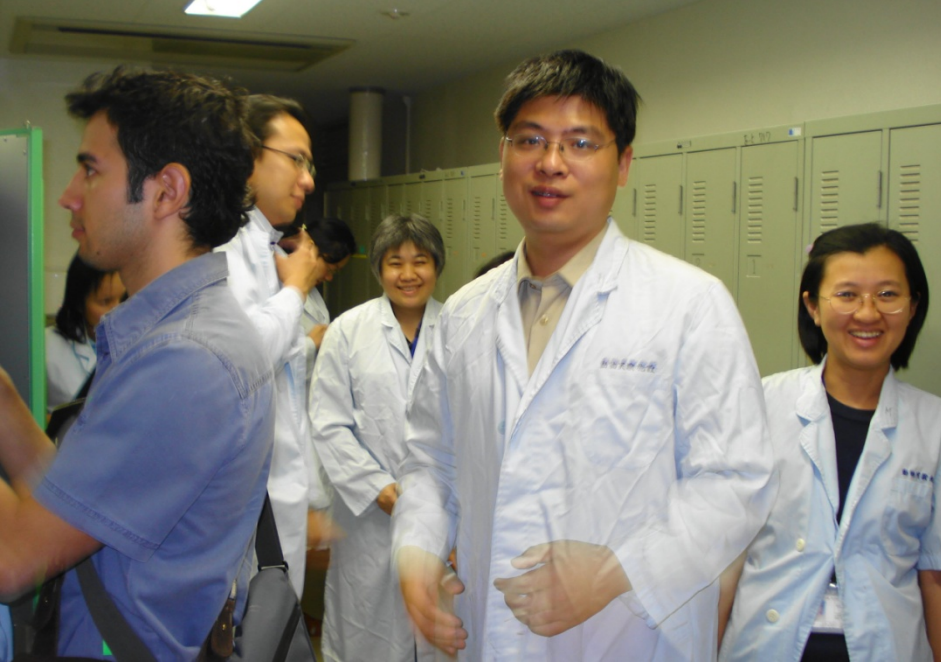
Soisanwan
Queensland Univ
Australia

Toxicology



Wongwiwat
Kon Koen Univ
Thailand

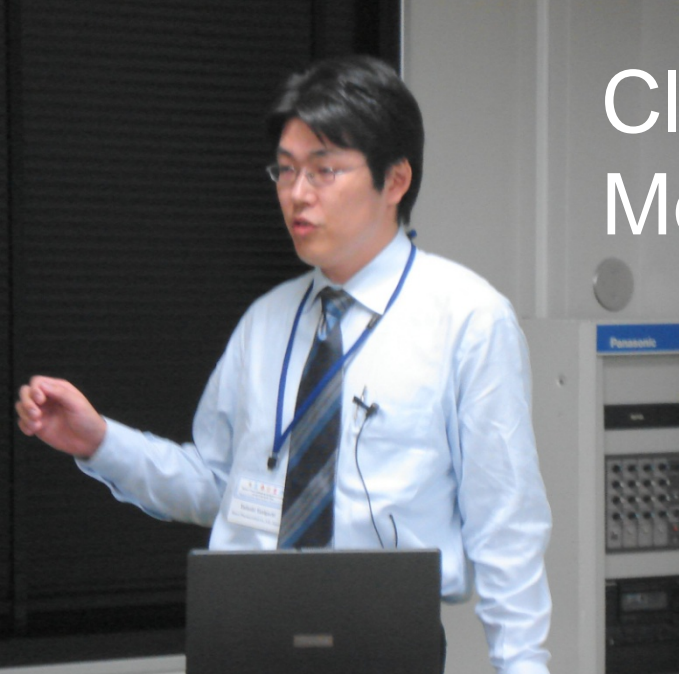
Animal Facility Nagasaki Univ Osawa

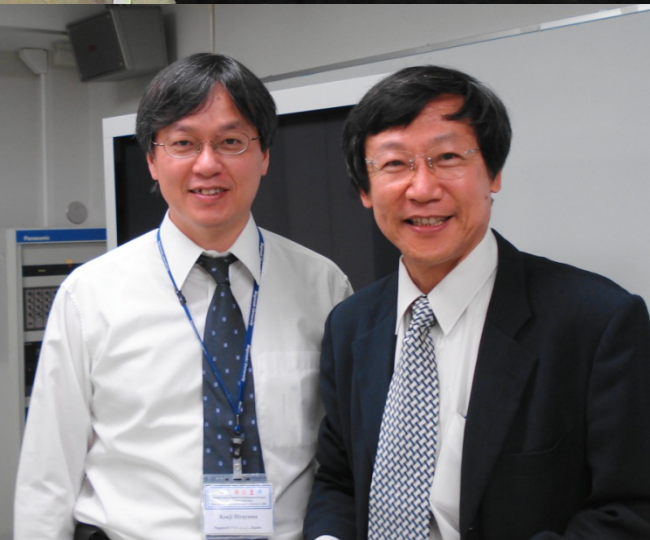


Osawa

Clinical Development Merck Banyu Japan

**Taniguchi
Kasamo**





Shyh-Yuh Liou
Japan Section GSK

Nonaka
Merck

Pharmacogenetics



Nonaka Merck Banyu
Clinical Development
Many examples



Jeyseelan
Study design
India
Many Statistics



**Miltefosine
Very much
Impressive!**



**Juntra
WHO/TDR**



FDA and PMDA

**Kawakami
Kyoto Univ**



Traditional Medicine



**Arai
Tsumura**



Tsutani Prof Univ.Tokyo




**Qin
China**



Half way!!





**Diploma Course on Research & Development
of Products to meet Public Health Needs**
Nagasaki University, Japan
October 2 - November 8, 2006

Jiraporn Thailand

Howard

Kenji

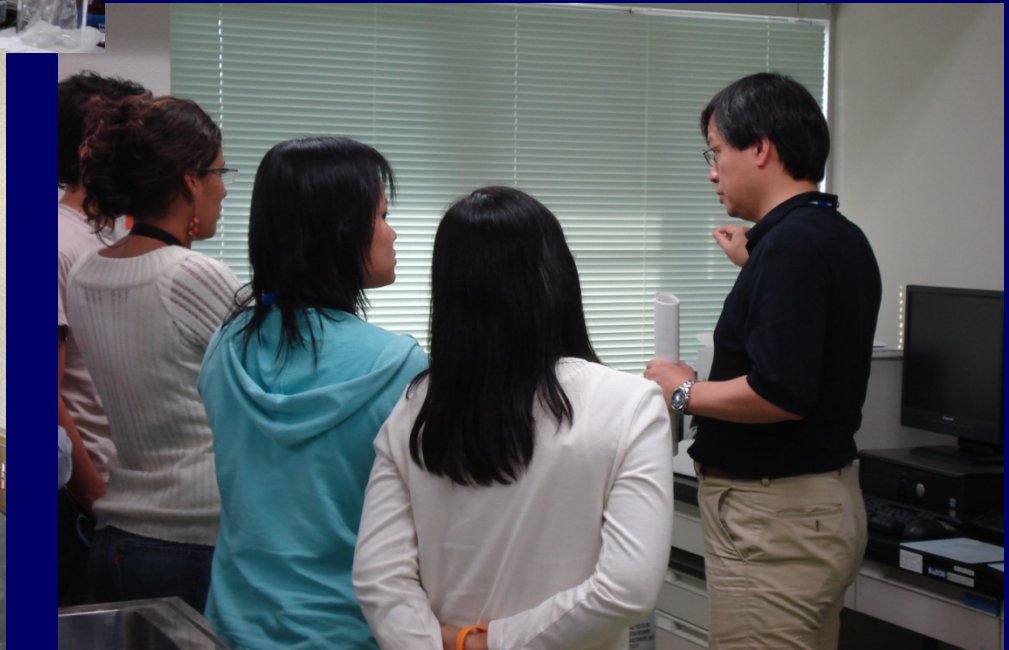


Module 3. Vaccine

Diploma Course on Research & Development
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Nagasaki University, Japan
October 2 - November 8, 2006



Vaccine Lab Visit ITM, Nagasaki Univ.



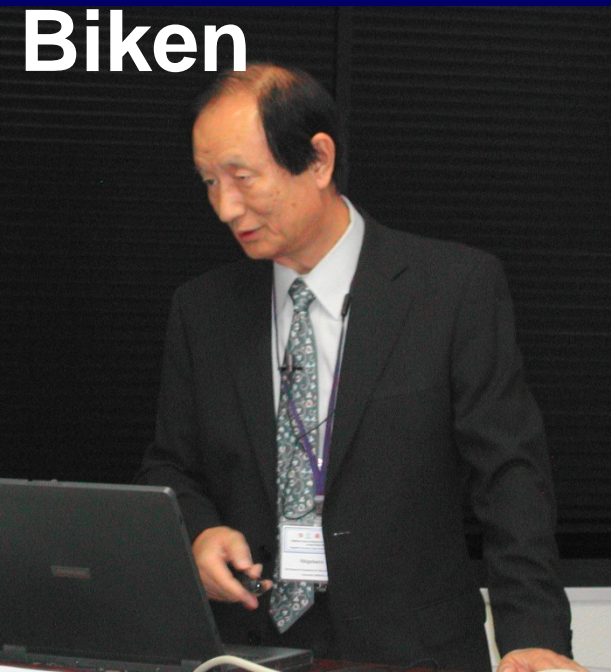


Pan

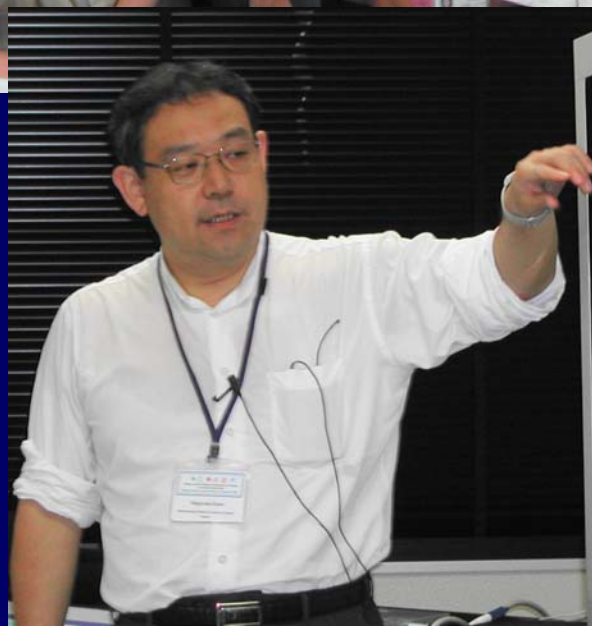
Malaria, Cholera, West Nile
Vaccines Ehara, Morita, ITM Nagasaki



**Arakawa
Ueda Ryukyu**



Biken



Horiuchi GSK

**Kano
IMCJ**



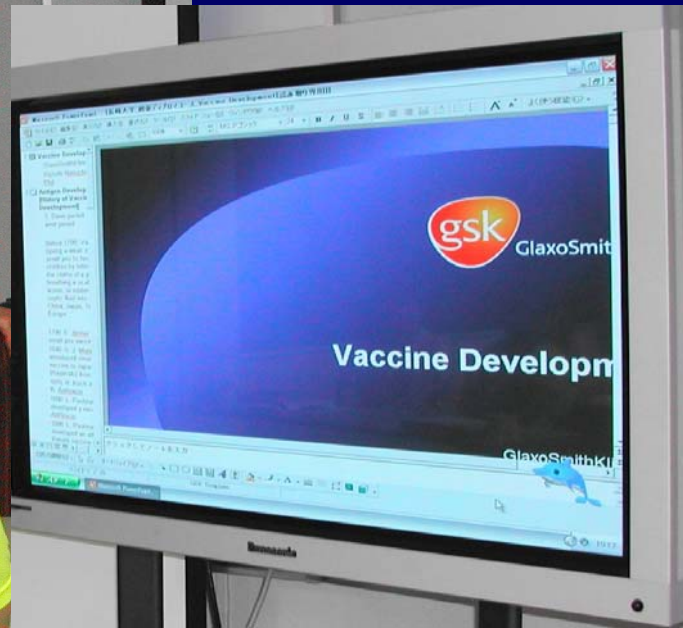
Yoshino GSK

Special Lecture
Tamiflu



**Shibasaki Prof
Univ Tokyo**

**Horiuchi, Iwasaki
GSK**



**Noro
GSK**





**Sasaki
Roche**



**Module 4
Diagnostic Tool
Development**

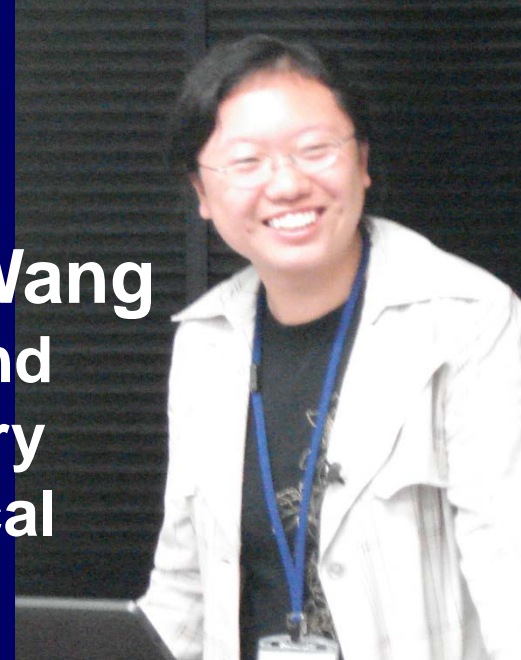




**Jose
Antioquia**



**Sankae
MOH**



**Lui Wang
Second
Military
Medical
Univ**

**Module 5
Data Management**



**Raja Gabal
Christian Med Univ**



**Charcrin
Thammasat**



**Kenji
FERCAP**



Vichai, MOH Thailand

**Module 6
GCP**



**Cristina
FERCAP
UP**



**Allan Johansen
Roche**



Vaccine Factory Kaketuken Kumamoto



Satoh

**Vaccine Factory
Kaketuken
Kumamoto**

GLP, GMP



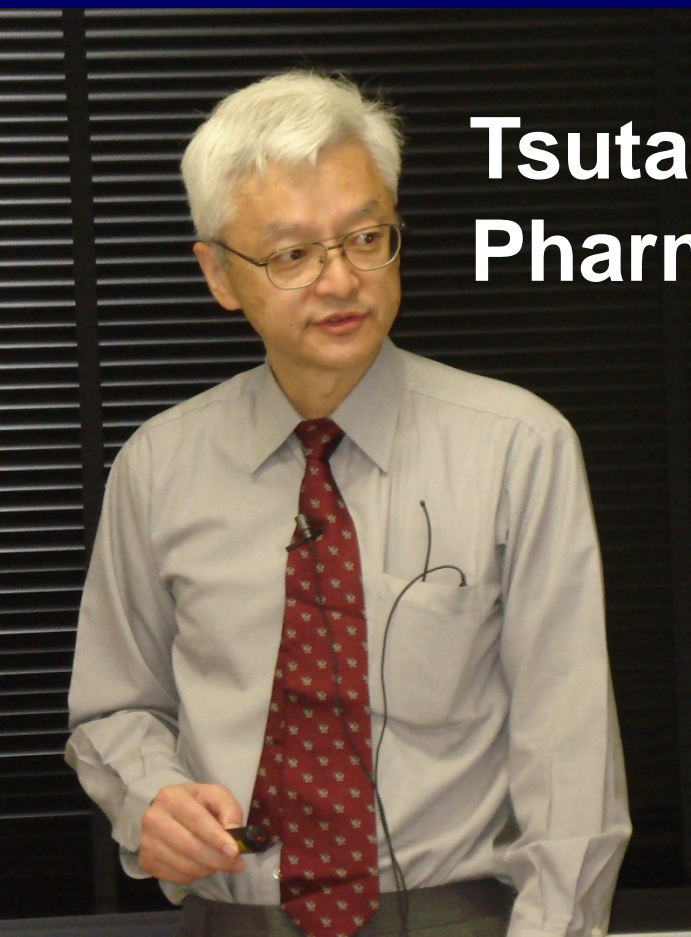
Vaccine Factory Kaketuken Kumamoto

GLP, GMP

Module 7
Post-registration
Activities



Kimura
Kanazawa
Univ.



Tsutani U.Tokyo
Pharmacoeconomics



Takahashi,
Merck Banyu

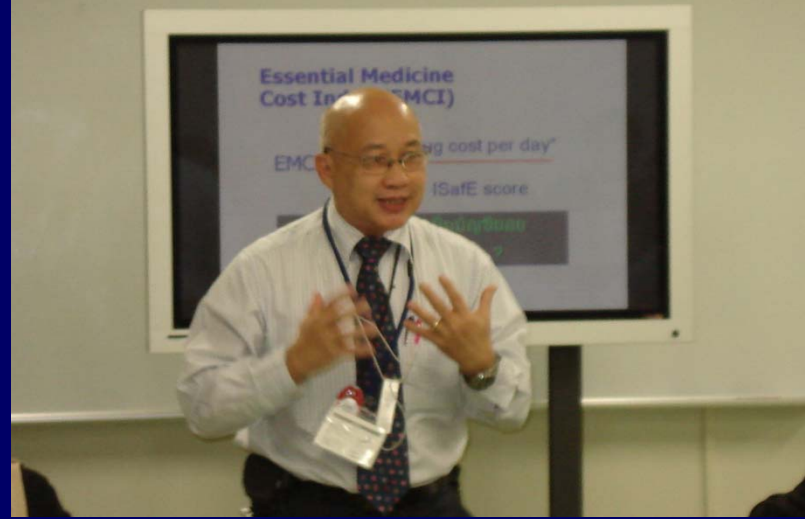
Public private partnership

Prof Chitr Public Health Needs

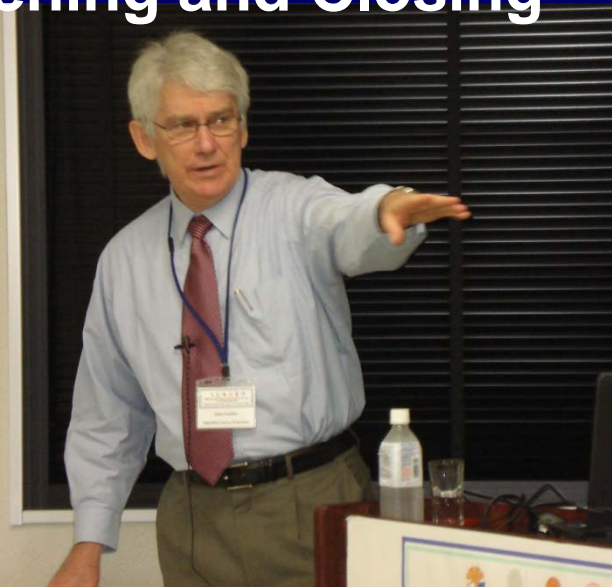




Prof Yamane
Policy Study
Univ
Intellectual
Property



Yanis
Opening and Closing



Yupin Thai FDA



Diploma Ceremony
November 8, 2006
ITM Nagasaki Univ.
Japan





**Diploma Ceremony
November 8, 2006
ITM Nagasaki Univ.
Japan**

Director General Hayashi of Ministry of Education
President Saito, Katamine Vice President, Aoki,
Tomonaga, Kohno, Matsumura, Deans, Institute of
Tropical Medicine, Graduate sch Medical Sciences,
Faculty of Medicine, Faculty of Pharmacy, Prof
Chitr of Chulalongkorn, Juntra, Janis of TDR,
Tsutani of Univ Tokyo, Yupin from Thai FDA
Takagi, Mizota, Hirayama Profs of ITM



Nagasaki University
Japan

Herby Confer The Degree of

DIPLOMA

on

Research and Development of Products
to Meet Public Health Needs

upon

Elaine Chen

for Having successfully completed the Diploma course
From October 2, 2006 to November 8, 2006
cooperated with Nanyang University, Chulalongkorn
University, Mahidol University, Second Military Medical
University, University of Antioquia and the Graduate School of
Pharmaceutical Sciences of the University of Tokyo in
collaboration with WHO/TDR and the Pharmaceutical Society of
Japan.

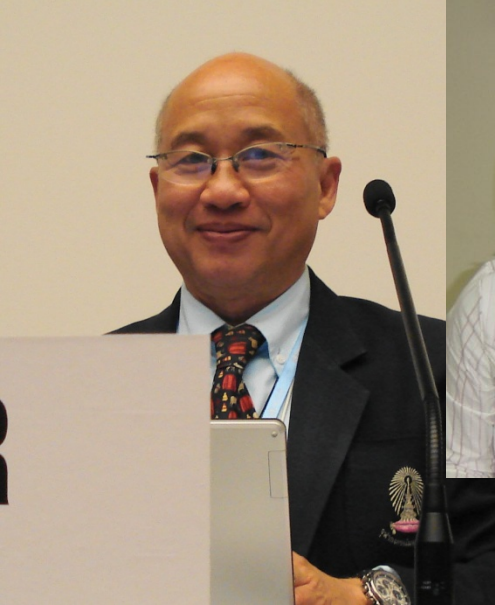
Hiroshi Saito, M.D.Ph.D.
President
Nagasaki University
Nagasaki, Japan

Keiji Hirayama, M.D.Ph.D.
Course Director
Institute of Tropical Medicine
Nagasaki University

Date of Issue: November 8, 2006
Serial No. C001

海外講師		所属	国内講師		
WHO	Janis Lazdins	長崎大学 学長	齋藤 寛	琉球大学 助教授	新川 武
WHO	Juntra Karbwang	長崎大学 コースディレクター	平山 謙二	GSK	堀内清
タイ・バイオテック助教授	Prasit Palitapongarnpim	昭和专业 教授	内田 英二	(株)GSK取締役開発本部副本部長	岩崎 甫
タイ・マヒドール大学教授	Supornchai Matangkasobat	東京 GSK	野呂 信弘	国立国際医療センター研究所適正技術開発・移転研究部	狩野繁之
タイ・コンケン大学助教授	Wongwiwat Tassaneeyakul	日本製薬医学医師連合会 会長	高橋 希人	大阪大学 名誉教授 BIKEN	上田重晴
オーストラリア・クィーンズランド大学	Soisanwan Satarug	長崎大学	片峰 茂	GSK	吉野泰
タイ・タマサート大学教授	Kesara Na Bangchang	長崎大学	芳本 忠	ロシュダイアグノスチック MD顧客サポート事業部	佐々木政人
クリスチャン医学大学教授	L. Jeeyaseelan	東京大学大学院教授	北 潔	東京大学大学院薬学系研究科長	柴崎正勝
中国・第二軍医学校 教授	Luping Qin	萬有製薬	大澤健一	金沢大学 大学院教授	木村和子
WHO	Howard Engers	長崎大学	畑山範	政策研究大学院大学 教授	山根裕子
中国第二軍医学校教授	Wei qing Pan	長崎国際大学教授	長岡寛明		
Fercap 教授	Cristina Torres	長崎大学	甲斐雅亮		
タイ政府 保健省審議官	Vichai Choikvivat	東京大学大学院	小野俊介		
オーストラリア・ロシュプロダクツ	Allan Johansen	アステラス製薬	伊東洋行		
タイ・タマサート大学	Charcrin Na Bangchang	大阪大学医学部	黒澤努		
中国第二軍医学校 医学部	Rui WANG	萬有製薬	谷口忠明		
Armauer Hansen Research Institute	Lawrence Yamuah	萬有製薬	野中健史		
タイ・タマサート大学 教授	Sangkae Chamnanawakit	萬有製薬	笠茂公弘		
コロンビア・アンチオキア大学	Jose Fernando Arango	GSK筑波装薬研究所	劉 世玉		
インド・クリスチャン医学大学 教授	Arunachalam Rajagopal	医薬品医療機器総合機構審議役	森 和彦		
タイ・チュラロンコン大学学部長	Chitr Sitthi amorn	東京大学 大学院	津谷喜一郎		
タイ厚生省	Pakdee Pothisiri	ツムラ(株)	新井一郎		
チュラロンコン大学 教授	Nijsiri RUANGRUNGSI	長崎大学	江原雅彦		
中国第二軍医学校 教授	Jia HE	長崎大学	森田公一		

Public 20%
Private 25%
Academia 55%



Chitr



Kesara



Kenji



Ivan



Juntra and Janis

Tsutani



Julia and Hu



Stakeholders of PD Diploma Course